

TAB 11A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 18
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

MAY 26, 2021

1 around 2007. Did you find any pattern or trend with the
2 same change or iteration with regard to McKesson?

3 **A.** Yes, I did.

4 **Q.** All right. So, all three companies had a Suspicious
5 Order Monitoring System in place up until somewhere around
6 2007 when there was a change in the policies that you found?

7 **A.** That's correct.

8 **Q.** Okay. Did you find any similarity or pattern amongst
9 the defendants for their policies and procedures for
10 suspicious order monitoring in the pre-2007 era?

11 **A.** I did, Your Honor.

12 **Q.** And have you prepared a slide that depicts a diagram of
13 your understanding of that type of system?

14 **A.** I did, Your Honor, hopefully to make it easier to
15 understand.

16 MR. FARRELL: And, Judge, I'd like to publish
17 Slide 11.

18 THE COURT: Okay. Slide 11? That's 12, isn't it?

19 MR. FARRELL: Yes, 12. Yes, Your Honor. And I
20 would ask and indulge the Court to allow Mr. Rafalski to
21 step down and to walk you through this slide, please.

22 THE COURT: You may do so, sir.

23 THE WITNESS: Simple illustration, Your Honor.

24 This is an order of pills. Here's the pharmacy Rx. They're
25 making an order to the distributor, making an order to the

1 distributor for the purchase of pills. That purchase of
2 pills from the distributor shipped down.

3 As it happened pre-2008, two things would happen. They
4 -- they would ship the pills and report to the DEA ARCOS and
5 this would indicate that they would ship these pills and
6 post-distribution, which meant after the pills had left the
7 distributor, they would submit an excessive purchase report
8 to the DEA. Some companies -- all companies did it on a
9 monthly basis and some companies did it on a daily basis.

10 **Q.** So, Mr. Rafalski, let's start with the ARCOS data.
11 When is the -- when is the ARCOS data reported based on your
12 experience?

13 **A.** Your Honor, it changed a little bit over time, but it's
14 been quarterly or monthly.

15 **Q.** And when we're talking about ARCOS data, please
16 distinguish the ARCOS data from the suspicious order
17 reporting.

18 **A.** The ARCOS data is required by regulation and it only
19 covers the Schedule IIs and the Schedule III narcotics
20 drugs; primarily for this case the hydrocodone.

21 **Q.** Is that what we're calling transactional data?

22 **A.** Yes, it is.

23 **Q.** And then this excessive purchase report, describe for
24 the Court your experience with excessive purchase reports
25 and what you found in the defendants' policies and

1 procedures related to the same.

2 **A.** How the system would work, Your Honor, is they would
3 calculate an average. Some of them would calculate an
4 average nationally or by distributor for a type of business.
5 So, in this case, it would be a pharmacy. They would
6 calculate this average over a 12-month period of data.

7 THE COURT: Mr. Schmidt?

8 MR. SCHMIDT: I didn't mean to interrupt. I'm
9 sorry, Mr. Rafalski.

10 THE WITNESS: That's okay.

11 MR. SCHMIDT: Maybe it was made clear, but I will
12 object as vague as to time frame.

13 THE COURT: Well, I'll sustain the objection. You
14 can ask him about the time frame. I'm not sure it is vague
15 based upon his previous testimony, but you can ask him.

16 MR. FARRELL: I can clarify.

17 MR. SCHMIDT: Thank you.

18 BY MR. FARRELL:

19 **Q.** To be clear, you're describing the systems that were in
20 place by each of the three defendants before 2007 or before
21 each of the defendants made a second iteration change of
22 their existing policies and procedures?

23 MS. MAINIGI: And, Your Honor, my objection on
24 behalf of Cardinal is a little bit different than Mr.
25 Schmidt's. I object to the extent -- I did hear him mention

1 that time period. To the extent this purports to represent
2 Cardinal's system in the pre-2007 time period, I object
3 because it is not accurate. It only reflects one step of a
4 two-step system.

5 MR. SCHMIDT: I think there's inaccuracy as to
6 McKesson, too, and the last question was compound.

7 MR. NICHOLAS: It is true that this slide does not
8 accurately reflect the pre-2007 system so we object on that
9 basis, as well.

10 THE COURT: Well, I think it goes to the weight
11 rather than admissibility of his testimony and you will have
12 ample opportunity to cross examine him on this and I will
13 allow you to go ahead, Mr. Farrell.

14 MR. FARRELL: Thank you. You can take your seat,
15 please.

16 THE WITNESS: Okay. Thank you, Your Honor.

17 BY MR. FARRELL:

18 **Q.** I think I've already distributed copies of this to the
19 parties. Mr. Rafalski, have we identified -- have you
20 identified a particular excessive purchase report that you
21 would like to use as a demonstrative for the Court?

22 **A.** Yes, sir.

23 **Q.** And for the record, this is P-14288ii. I believe it's
24 already admitted in the record. Copies have been provided
25 from counsel.

1 May I approach?

2 THE COURT: Yes.

3 THE WITNESS: Thank you.

4 MR. FARRELL: Would you please bring back up the
5 last slide?

6 You may not want to put it away just yet, Judge. I'm
7 going to make a particular point.

8 THE COURT: Okay.

9 BY MR. FARRELL:

10 Q. So, in general, Mr. Rafalski, we've heard testimony
11 about excessive purchase reports that were submitted by the
12 defendants to the DEA.

13 A. That's correct, Your Honor.

14 Q. And is this one such report?

15 A. Yes, it is, Your Honor.

16 Q. And, in fact, is this one report and, in particular,
17 Cardinal Health from their Wheeling Distribution Center?

18 A. Yes, it is.

19 Q. And is this for one month from one distribution center?

20 A. I believe it is, yes, sir.

21 Q. Okay. And where would this report have been sent?

22 A. It would have been mailed or delivered, but primarily
23 mailed to each of the DEA Offices in the areas. Or for
24 Wheeling, it would have been mailed to the nearest DEA
25 Office that would have covered the Wheeling Distribution

1 Center.

2 Q. So, by drawing the timeline here, around 2007 for each
3 of the defendants, it was a little bit different, but
4 between the first and second iteration of their SOMS policy,
5 were each of the defendants in practice receiving orders
6 from a pharmacy, shipping the order, and thereafter
7 reporting the transaction to the ARCOS data, and then
8 publishing these after-the-fact reports based on some metric
9 to the DEA?

10 MR. SCHMIDT: And we'll object. He's not here as
11 a fact witness and his testimony directly contradicts the
12 testimony, for example, of a fact witness that was here just
13 yesterday.

14 MR. FARRELL: Judge, if I may, this is not a
15 proper --

16 THE COURT: Let me hear from Ms. Mainigi.

17 MS. MAINIGI: Your Honor, my objection is that Mr.
18 Farrell -- we've indulged Mr. Farrell in leading this
19 witness because we know everybody wants to get through the
20 testimony, but he's both testifying and leading the witness
21 at this point.

22 THE COURT: Mr. Nicholas?

23 MR. NICHOLAS: I would just join. Join.

24 THE COURT: Well, you can ask him leading
25 questions to get him through this, Mr. Farrell, but don't

1 testify. I mean, don't give him the answer in your
2 question.

3 MR. FARRELL: Yes, Your Honor.

4 THE COURT: Okay.

5 BY MR. FARRELL:

6 Q. So, is what we're -- what I'm holding in my hand from
7 Cardinal Health an exemplar of an after-the-fact report to
8 the DEA?

9 A. That's correct, yes, it is.

10 Q. And have you studied the criteria or have you found
11 evidence in the record of the criteria that Cardinal Health
12 was used -- using pre-2007 for how you wound up on their
13 ILR?

14 A. I did.

15 Q. Okay. I would ask you to turn to Page -- Bates stamp
16 117 on the bottom.

17 A. Okay. I'm there, Your Honor.

18 MR. FARRELL: Judge, what I'm looking at is in the
19 right-hand corner. It says 117. You don't need to actually
20 pull it up. I can put it on the camera, if you would like.

21 THE COURT: Okay.

22 BY MR. FARRELL:

23 Q. So, when you're looking at this document -- let me see
24 if I can get it a little more square.

25 Walk through for us what it is this document is

1 intending to communicate.

2 **A.** Your Honor, this is part of the report, and this is
3 specific for a customer. So, a little bit down where you
4 see the little dots it starts -- I'll take that particular
5 customer. Customer number, Medicine Shoppe number 290,
6 Huntington. It has the address, 2402 Adams, Huntington,
7 West Virginia. That would be the customer that's purchasing
8 these products from Cardinal Health.

9 **Q.** And what was the run date or the date that this was
10 report was run?

11 **A.** May 6th of 2007.

12 **Q.** And what is the time frame that this report is
13 intending to cover?

14 **A.** April of 2007.

15 **Q.** All right. And so, when you look at the report down at
16 the bottom right-hand corner, do you see this ingredient
17 limit?

18 **A.** I do.

19 **Q.** Total grams. Do you see that here, total grams?

20 **A.** I do.

21 **Q.** Through -- through your review, have you been able to
22 determine what an ingredient limit is in Cardinal Health's
23 program?

24 **A.** I did.

25 **Q.** What is an ingredient limit?

1 **A.** So, that's the -- the actual trigger or threshold that
2 they have calculated. If you look below April, 2007, Your
3 Honor, you will see the factor used as four and for Cardinal
4 Health they would create an average for the distribution
5 center of the distribution of oxycodone products. They'd go
6 back 12 months and create an average and then they would
7 times it by four. And that four would be the ingredient
8 limit number at the very bottom, 104.82.816 grams. So, that
9 essentially is four times the average of the pharmacies that
10 they -- they took into consideration from that distributor.

11 **Q.** So, to be clear, every month Cardinal Health was
12 running this document and they were taking the average
13 retail pharmacy from that distribution center, they were
14 multiplying it by --

15 THE COURT: Ms. Mainigi?

16 MS. MAINIGI: Mr. -- Mr. Farrell is testifying at
17 this point.

18 MR. FARRELL: I'm trying --

19 MS. MAINIGI: And summarizing.

20 MR. FARRELL: I'm summarizing, yes, Judge.

21 THE COURT: Well, I'm going to overrule the
22 objection and let you do it. I don't think this is
23 misleading and we're getting him through his testimony and
24 it's complicated and I need to understand it so I'm going to
25 let you do it, Mr. Farrell.

1 MR. FARRELL: Thank you.

2 BY MR. FARRELL:

3 Q. So, Cardinal Health on a monthly basis, and this would
4 be performed in May, but for the April transactions, would
5 take the average from the retail pharmacies serviced by that
6 distribution center and multiply it by four, correct?

7 A. That's correct.

8 Q. And, in this instance, that means 140 grams would be
9 the ingredient limit, which is four times the average
10 pharmacy the Wheeling Distribution Center was servicing?

11 A. That's correct, Your Honor. Your Honor, the total --
12 the grams column, do you -- do you need me to explain what
13 those are to you?

14 MS. MAINIGI: Perhaps Mr. Farrell can ask a
15 question.

16 THE WITNESS: Oh, sorry.

17 THE COURT: Yes. I --

18 MR. FARRELL: Yes, sir. Yes, sir.

19 THE COURT: Go ahead.

20 THE WITNESS: I'm sorry, Your Honor.

21 BY MR. FARRELL:

22 Q. So, before we get there, what we have -- what would you
23 describe this ingredient limit, this 104 grams, what does it
24 mean?

25 A. The 104 grams is the actual active narcotic amount

1 that's contained in four times the average, 12-month
2 average.

3 **Q.** And so --

4 THE COURT: Let me interrupt you. I'm unclear as
5 to what an excessive purchase is and how -- what the basis
6 is for determining if a purchase is excessive. Are you
7 getting there?

8 MR. FARRELL: I'm trying to, yes, Your Honor.

9 THE COURT: Okay.

10 BY MR. FARRELL:

11 **Q.** So, the ingredient limit of 104 grams is four times the
12 average of the retail pharmacies for that month for this
13 distribution center, correct?

14 **A.** That's correct.

15 **Q.** And was Cardinal Health using that as a benchmark to
16 determine what an excessive order was?

17 **A.** Yes. It would monitor the purchases of each of its
18 customers and any customer that exceeded that 104.82816
19 would fall onto the list.

20 **Q.** Now, this particular customer in Huntington, West
21 Virginia and for oxycodone-based drug, you'll see here a
22 list of all of the orders from that month from The Medicine
23 Shoppe to Cardinal Health, correct?

24 **A.** Yes.

25 **Q.** And what type -- can you walk through briefly the types

1 of drugs that were ordered here?

2 **A.** This is specific for oxycodone products, Your Honor.
3 So, every product that's on this list is -- contains
4 oxycodone. The first one, Roxicet, those are combination
5 drugs, five milligrams of oxycodone and 325 milligrams of
6 acetaminophen.

7 You fall down below the next three. Those are
8 OxyContin drugs. Those are -- contain just oxycodone. And
9 so, the 80 milligrams would be the active ingredient of
10 oxycodone in each pill.

11 **Q.** So, let's -- let's stop right there for a second and
12 give just one example. So, if we're looking at one
13 particular transaction here, this would be a quantity of
14 four, 100 tabs of Oxy 80s, correct?

15 **A.** Yes.

16 **Q.** So, that's a particular request or transaction for 400
17 oxy 80 tabs?

18 **A.** That's correct, Your Honor.

19 **Q.** Now, in the far right-hand corner what Cardinal Health
20 has done is they've taken the active ingredient for each of
21 these orders and then totalled them for a customer total; is
22 that right?

23 **A.** That's correct.

24 **Q.** So, in this month of April, 2007, Cardinal Health
25 shipped to The Medicine Shoppe 157 grams of oxycodone,

1 correct?

2 **A.** That's correct.

3 **Q.** And after shipping it, it then reported to the DEA and
4 this report that that month exceeded the cap of 104 grams?

5 **A.** Yes. The 104 grams, Your Honor, didn't stop the
6 distribution. It was just the measure of when to place
7 these customers onto this list.

8 THE COURT: I need to stop you. My realtime has
9 gone awry.

10 COURT REPORTER: Can I have one minute, please?

11 THE COURT: Yes.

12 (Pause)

13 COURT REPORTER: Is it on now?

14 THE COURT: Yes.

15 COURT REPORTER: I think something -- it's sorted
16 out. Okay.

17 BY MR. FARRELL:

18 **Q.** So, using --

19 MR. FARRELL: I'm sorry, Judge. May I continue?

20 THE COURT: Yes.

21 BY MR. FARRELL:

22 **Q.** So, using this as an exemplar, The Medicine Shoppe
23 would be the pharmacy, correct?

24 **A.** That's correct.

25 **Q.** And it made orders from Cardinal Health?

1 **A.** That's correct.

2 **Q.** And all of those orders got shipped that are on that
3 list?

4 **A.** That's correct.

5 **Q.** Those orders, either on a monthly or quarterly basis,
6 the transactions would be reported to the ARCOS database,
7 correct?

8 **A.** Yes.

9 **Q.** And because the orders for that month from this
10 pharmacy exceeded four times the average, this pharmacy got
11 included in an excessive purchase report sent to the DEA?

12 **A.** That's a correct statement, Your Honor.

13 **Q.** And so, whether you call it an ingredient limit report
14 or an excessive purchase report, the defendants pre-2007
15 were identifying some type of threshold that if you exceeded
16 it, got reported to the DEA?

17 THE COURT: Mr. Schmidt?

18 MR. SCHMIDT: And, Your Honor, he's giving very
19 specific testimony about Cardinal. If he's going to make
20 these sweeping assertions, he should give the similar
21 testimony about McKesson, and I assume ABDC is taking the
22 same view.

23 MS. MAINIGI: And, Your Honor, I have a continuing
24 objection because his testimony seems to reflect that
25 there's only a one-step process and there was a two-step

1 process.

2 MR. FARRELL: Judge, if I may, these are --

3 THE COURT: Let me hear from Mr. Nicholas before
4 that.

5 You go ahead.

6 MR. NICHOLAS: I just join in both objections as
7 are articulated. I don't need to re-state them.

8 THE COURT: Mr. Farrell?

9 MR. FARRELL: These are improper objections, Your
10 Honor. To stand up and say that I'm wrong is not the
11 appropriate time for this. They have the opportunity to get
12 up and cross and ask these questions.

13 THE COURT: Yeah. I'll overrule the objection.
14 Let's press on.

15 BY MR. FARRELL:

16 **Q.** Mr. Rafalski, sometime around the year 2007 from your
17 prior testimony each of the three distributors changed the
18 way in which they were performing their suspicious order
19 monitoring, correct?

20 **A.** That's correct, Your Honor.

21 **Q.** Have you prepared a diagram that illustrates the design
22 of the system used or the common design features used by
23 each of the three defendants after 2007?

24 **A.** Yes, I have.

25 MR. FARRELL: And, Judge, at this time what I

1 would like to do is I would like to publish the second half
2 of this slide and ask Mr. Rafalski to step down and describe
3 it for the Court.

4 THE COURT: You may do so.

5 THE WITNESS: Thank you, Your Honor.

6 Ready, Your Honor?

7 MR. FARRELL: Hold on.

8 THE WITNESS: As -- as the previous, this is the
9 pharmacy and this is an order that's transmitted to the
10 distributor for purchase of controlled substances. Upon --
11 prior to the shipment, we now have the change in the system.
12 This is a Suspicious Order Monitoring System. You can kind
13 of characterize it as a little computer or little box.
14 Built into that is a way that they monitor the flow of drugs
15 and calculate the amounts and this makes a decision.

16 There's a trigger or threshold that's set inside of
17 this system and if it's below the trigger of the threshold,
18 the purchase flows through, goes to ship, and the -- and the
19 company also reports to ARCOS.

20 If it -- if it triggers the system, in other words,
21 like the ingredient limit report, if it hits that threshold,
22 it stops the order and it now holds it as part of this
23 system.

24 BY MR. FARRELL:

25 Q. Now, Mr. Rafalski, once the system holds an order, how

1 -- what is the design process that's supposed to follow?

2 **A.** So, when we talk about a suspicious order, Your Honor,
3 the suspicion is that this order could be diverted. In
4 other words, it could fall into illicit hands. The
5 maintenance of effective controls to prevent diversion is
6 what's the key issue here in that the company has -- has --
7 takes this held order and they make a decision on whether
8 they're going to ship it.

9 Part of that decision process is commonly called due
10 diligence. It's an internal investigation where they look
11 at some internal information and facts and circumstances,
12 take some action as warranted, and the company would make a
13 decision.

14 If they believe that this suspicion is dispelled, that
15 dispels the potential for diversion, then that order would
16 flow down to the customer and also be reported to ARCOS.

17 If, in fact, they conduct this investigation and they
18 can't clear or dispel the suspicion, then that order would
19 be blocked and cancelled and it would be reported to the
20 DEA.

21 MR. FARRELL: Thank you. Take your seat, please.

22 MS. MAINIGI: Your Honor, my objection is just the
23 characterization of the testimony is on its face different
24 from the characterization of the chart. There is the
25 shipped order and the held order. At that point, there's no

1 the game. These are -- these are flagged orders, but they
2 are not suspicious orders, and that's an important
3 distinction and I think the record has to be clear on that.

4 THE COURT: Well, these are things that can be
5 cleared up on cross, it seems to me, and I'm going to allow
6 you to go ahead. Overruled.

7 Go ahead, Mr. Farrell.

8 MR. FARRELL: All right.

9 BY MR. FARRELL:

10 Q. So, in your analysis did you rely upon the fact that a
11 triggering order should block all future orders of the same
12 drug type?

13 A. Yes.

14 Q. And if the system is working as designed, there's an
15 immediate process to be able to determine whether to ship or
16 block?

17 A. That's correct, Your Honor.

18 Q. And if you ship, that means you have cleared the
19 suspicion that it's being diverted, correct?

20 A. That's correct, Your Honor.

21 Q. And if you block it, that means you're suspicious these
22 pills are getting diverted?

23 A. You -- you've conducted your due diligence and you
24 can't dispel the suspicion, the potential for diversion,
25 Your Honor.

1 Q. Now, to be clear --

2 THE COURT: And your testimony is that that was
3 built into the system here that all three of these
4 defendants had in place?

5 THE WITNESS: Yes, sir. Starting between 2007 and
6 2008, they all designed a system to do exactly that.

7 THE COURT: But that was your understanding of
8 what the system was and what it was designed to do?

9 THE WITNESS: In general terms, yes, sir.

10 THE COURT: Go ahead, Mr. Farrell.

11 BY MR. FARRELL:

12 Q. So, the system is designed to have a trigger, correct?

13 A. Yes.

14 Q. Now, if you set that trigger at ten pills a month,
15 based on your experience, how many times will this system go
16 ding, ding, ding?

17 A. A lot because they don't sell pills in -- ten pills.
18 So, usually, the smallest amount is a hundred, generally
19 speaking. There's some drugs that are a little smaller.
20 So, every transaction would go ding, ding, ding, Your Honor.

21 Q. And if you set this trigger at 40,000 pills a month,
22 how many times would the system go ding, ding, ding?

23 A. It wouldn't until you bought 40,000 and 100 pills, Your
24 Honor.

25 Q. And so, based on your experience -- well, no. I'm

1 going to back up a minute. We'll circle back to that.

2 So, what we're going to do now is we're going to talk
3 about the different triggers that you have seen from your
4 investigations, as well as from your review of this case.

5 Before we get there, just to be clear, once the system
6 triggers, the order should be held until due diligence can
7 make sure it's not being diverted, correct?

8 **A.** Yes. Yes, Your Honor, that's my opinion.

9 MR. FARRELL: Judge, this is a bigger block that
10 we're about to go into, if you'd want to take a break.

11 THE COURT: Well, does anybody need a break?
12 We've already taken one this morning.

13 MR. FARRELL: I'm good.

14 THE COURT: Let's go forward full speed ahead, Mr.
15 Farrell.

16 MR. FARRELL: Yes, sir.

17 All right. Let's go to the next slide, please. Wait,
18 no. Don't do that.

19 BY MR. FARRELL:

20 **Q.** Mr. Rafalski --

21 **A.** Yes, Mr. Farrell?

22 **Q.** Have you identified methodologies by which registrants
23 have used or you have experienced or seen as a triggering
24 mechanism for their SOMS?

25 **A.** Yes, I have.

1 **Q.** And have you prepared a slide that identifies the
2 various methodologies that you have employed when reviewing
3 data?

4 **A.** I have, Your Honor.

5 **Q.** And would looking at that slide assist you in your
6 testimony with the Court?

7 **A.** Yes, it would.

8 MR. FARRELL: Judge, if permitted, I would like to
9 publish slide 14.

10 Okay. I know that this is -- this is the slog. And
11 so, Judge, I'm going to try to be very methodical, but this
12 is -- this is a technical portion.

13 THE COURT: All right.

14 BY MR. FARRELL:

15 **Q.** Mr. Rafalski, is there one particular golden rule on
16 what the trigger should be?

17 **A.** No, Your Honor.

18 **Q.** Okay. Describe for the judge what guidance is
19 available out there for how high to set the trigger or how
20 low to set the trigger.

21 **A.** Well, that determination, Your Honor, is for the
22 company, the registrant. The regulation, the suspicious
23 order monitoring regulation, speaks to it and it says that
24 they would typically be trying to identify orders of unusual
25 size, deviating substantially from a normal pattern or an

1 unusual frequency.

2 In the cases of these systems, they're only looking at
3 the volume and it's a critical decision to try to determine
4 for each customer what would be the usual amount of drugs
5 that they were purchasing.

6 **Q.** Now, have you been privy to the actual computer code
7 algorithm used by each of the defendants inside their
8 suspicious order monitoring systems?

9 **A.** It was not provided as part of the litigation, Your
10 Honor.

11 **Q.** But based on your experience as a DEA investigator,
12 have you been able to generally replicate what that number
13 should look like?

14 **A.** I'm not sure I understand your question, what -- what
15 the numbers should look like.

16 **Q.** The threshold.

17 **A.** It would be calculated to depend on what the system is
18 or how they designed the system.

19 **Q.** And have you been able to discern how each of these
20 systems have been generally designed?

21 **A.** Yes, I have.

22 **Q.** Now, to be clear, how many different systems are
23 possible?

24 **A.** It would be a huge number, Your Honor, because you have
25 to take in consideration the range of types of registrants

1 that could purchase. So, if you're distributing drugs to a
2 hospital, you could be looking at a large number. You could
3 be distributing drugs to a veterinarian, a veterinarian's
4 office. He would have the ability -- he or she would have
5 the ability to purchase drugs.

6 So, there, you would be looking at a smaller amount and
7 a smaller type, a different type. Veterinarians wouldn't
8 have use for drugs like Adderall. So, it's my belief that
9 the regulation, the way it is, allows the flexibility for a
10 registrant to desire a -- design a system to meet their
11 business needs and to service their customers.

12 **Q.** So, this gets back to purpose. When we're designing
13 this trigger, when we're designing this function, this
14 threshold, this algorithm at the stage of the transaction,
15 what is it that we're trying to flag? What's the purpose of
16 flagging certain orders?

17 **A.** We're trying to identify an order, Your Honor, that has
18 a suspicion of diversion, that is outside of what's normal
19 and what's usual.

20 **Q.** So, looking at this, have you identified several
21 different methodologies and then -- and then applied those
22 methodologies to the data?

23 **A.** I have.

24 **Q.** And so, in general, will you identify for the record
25 what each of these, A, B, C, D, E and F are? We're talking

1 a hundred thousand feet looking at it because we're going to
2 walk through each of them.

3 **A.** The first one, Your Honor, is maximum monthly trailing
4 six-month threshold. That is the system that was used by
5 Masters Pharmaceutical that was discussed in the DC
6 appellate ruling.

7 B, that's a -- the trailing six-month maximum monthly
8 fixed after first triggered threshold. That's a repeat of
9 the Masters system, but used in my review, it's going to be
10 used a little differently. I think we're going to explain
11 that.

12 The third one, C, twice trailing 12-month average,
13 that's based on the Mallinckrodt system that was in the
14 litigation in one of the other cases.

15 D, three times the 12-month average is ABDC and
16 Cardinal. Was used at one of the systems that they used in
17 the time periods I showed you earlier.

18 MS. MAINIGI: Objection, Your Honor, to the
19 testimony. That is outside the scope of his report. It was
20 not identified. His number -- or his letter D methodology
21 was not disclosed in his report as identified with Cardinal.

22 THE COURT: Mr. Farrell?

23 MR. FARRELL: Judge, I'm not quite sure how to
24 respond to that. It's an enormous report. But I think it
25 was undisputed that Cardinal was running a three-times

1 THE COURT: Well, I think I've -- I've got it so
2 far. So, let's move on to the next step.

3 MR. FARRELL: Yes, Your Honor. I apologize.

4 BY MR. FARRELL:

5 Q. So, now let's move on to C, twice trailing 12-month.

6 A. Can I make a correction on the previous one?

7 Q. Yes.

8 A. On the B methodology? So, it doesn't -- it doesn't
9 stop --

10 MR. SCHMIDT: I didn't mean to interrupt.

11 THE COURT: Yeah. Go ahead.

12 MR. SCHMIDT: But I would like to say something
13 after.

14 THE WITNESS: It doesn't cut all of those orders
15 and only ship that amount. It would only ship the orders
16 that didn't exceed that red line.

17 THE COURT: Okay, Mr. Schmidt.

18 MR. SCHMIDT: And that's what I flagged, Your
19 Honor. That's my concern with the leading. He actually led
20 him into improper testimony that had I not objected would
21 stand on the record.

22 MR. FARRELL: Well, Judge, I would think that his
23 objection is what led him into this.

24 THE COURT: Well, I'm going to overrule the
25 objection at this point and you can go ahead.

1 MR. FARRELL: All right.

2 BY MR. FARRELL:

3 Q. So, twice trailing 12 months, please walk the judge
4 through how that type of methodology would be employed.

5 A. Your Honor, if we go back to the chart and you see the
6 transaction that would flow from month 1 to month 12, we get
7 to month 12 and that's the trailing 12 months. So the
8 system would look back to 12 months. It would take each of
9 the monthly transactions and create an average. And then it
10 would take two times of that average.

11 Generally, in this kind of an illustration, that would
12 be right around six, month 6 approximately. So, it would be
13 two times of month six.

14 Q. So, backing up, the 12-month average, average of what?

15 A. Distribution of pills. Each one of those bars
16 represent the number of pills that go out each month but,
17 Your Honor, this is -- it's trailing 12 months so --

18 Q. Mr. Rafalski, hold on a second. Average of that
19 customer? Average of that region? Average of that nation?
20 What is it an average of?

21 A. It depends how they -- how they set it, how the company
22 sets it. They could set it by groups of pharmacies,
23 individual pharmacies. And how we applied it, or how I
24 applied it, actually, in the methodology was it was applied
25 -- in one segment of time of the analysis, it was the State

1 of West Virginia transaction average. And there was a
2 section during ARCOS period where it was the national
3 average. And it would be two times the national average, if
4 that answers your question --

5 **Q.** I think so.

6 **A.** -- about the methodology or about the example.

7 **Q.** Now, when we say the word trailing, explain to the
8 judge what that terminology, that lexicon means, trailing?

9 **A.** So, as the transactions, Your Honor, move left to
10 right, when it goes to month 13, month 1 just falls off and
11 it recalculates the average. And it would continue to do
12 that function system from that point on.

13 **Q.** Now, under D, three times 12-month average, how does
14 that work?

15 **A.** It essentially is the same description I gave you, Your
16 Honor, for the -- for the previous, the two times, but this
17 time it would go three times the average.

18 And, Your Honor, just for the illustration, the line
19 wouldn't go straight across because, as the next month hit,
20 as this chart is illustrated, it would bump up a little bit
21 each time.

22 **Q.** All right. Now, let's go to E, maximum 8,000 dosage
23 units. Tell me how putting a threshold cap should work.

24 **A.** That's what this describes. In this case, there was a
25 decision that the maximum amount of drugs that could be

1 oxycodone dosage units.

2 For hydrocodone, 16,159,150, or 90.2 percent.

3 Finally, at the bottom, McKesson, for oxycodone
4 2,098,560, 52.7 percent.

5 And for hydrocodone dosage units, 2,484,640, or 66.6
6 percent.

7 **Q.** And, finally, the last methodology, F, the pickers and
8 packers maximum daily dosage units, would you please report
9 to the Court your findings?

10 **A.** AmerisourceBergen for oxycodone dosage units,
11 12,459,020, 97.3 percent.

12 For hydrocodone dosage units, 22,582,020, or
13 99.8 percent of dosage units.

14 Cardinal Health for oxycodone, 16,527,880 dosage units,
15 or 96.2 percent.

16 For hydrocodone, 17,688,100, or 98 percent of dosage
17 units.

18 McKesson for oxycodone dosage units, 3,713,000, or
19 93.2 percent dosage units.

20 And for hydrocodone dosage units, 3,648,650, 97.9
21 percent.

22 **Q.** Very good. Now, Mr. Rafalski, this -- these numbers
23 that you've just read into the record --

24 **A.** Yes, sir.

25 **Q.** -- are in the -- you're using the assumption that there

1 is no due diligence and this is what should have happened
2 when the fire alarm went off, correct?

3 **A.** Assuming no due diligence. What -- I don't --

4 **Q.** So -- so, have we asked you to review all of the due
5 diligence files made available in this litigation?

6 **A.** Yes, sir, you have.

7 **Q.** And have you identified them in your reliance
8 materials?

9 **A.** I have, Your Honor.

10 **Q.** And have you gone through the customer files and the
11 documents produced by AmerisourceBergen, McKesson and
12 Cardinal Health?

13 **A.** I have, Your Honor.

14 **Q.** And have you found sufficient evidence in the record to
15 dispel the suspicion of any of these orders that -- that
16 were or should have been flagged?

17 **A.** I have not, Your Honor.

18 **Q.** Now, let's go to -- did we ask you to review the actual
19 suspicious orders that were reported and disclosed by the
20 defendants in this litigation?

21 **A.** Yes. I'm not sure you asked me to. I mean, that was
22 part of what I did as part of my review of all of the
23 material, but that was one of the primary things that I
24 looked at.

25 **MR. FARRELL:** Can we please bring up at that

1 AmerisourceBergen slide?

2 BY MR. FARRELL:

3 Q. Mr. Rafalski, you previously testified that there were
4 77,398 transactions by AmerisourceBergen with pharmacies in
5 Huntington-Cabell County, West Virginia. Based on your
6 review of the files, how many of those transactions were
7 reported by AmerisourceBergen to the DEA as suspicious?

8 A. As listed there, Your Honor, by year, I believe that
9 total is 45.

10 Q. And will you read into the record each of the years and
11 the numbers?

12 A. 2007, 2 pre-shipping reporting; 2008, 4 pre-shipment
13 reporting; 2009, 12 pre-shipment reporting; 2010, 5
14 pre-shipment reporting; 2011, 1 pre-shipment reporting;
15 2012, 4 pre-shipment reporting; and 2013, 11 pre-shipment
16 reporting. And there were -- no reporting post-shipment.

17 Q. How about -- I'm told that you missed 2014.

18 A. Oh, I'm sorry. Your Honor, 6 for 2014.

19 Q. And then, in 2015, '16, '17 and '18, how many were
20 there?

21 A. There were 0, Your Honor.

22 Q. So, out of the 77,000-plus transactions, what's the
23 total number of orders reported as suspicious?

24 A. 45.

25 Q. Now, what is it that we're suspicious of? Let's talk

1 to the judge briefly. Why are -- what are we suspicious of
2 happening?

3 **A.** Diversion. Potential for diversion, Your Honor.

4 **Q.** Diversion of what?

5 **A.** Of the controlled substances, that they could leak or
6 be not used properly. It would be an illicit use.

7 **Q.** And so, if you're suspicious, are you suspicious of the
8 orders more likely than not being diverted into the illicit
9 market?

10 **A.** That's correct. If you don't dispel the suspicion of
11 that order and of future orders, if you hadn't removed that
12 suspicion of diversion or dispelled it, more likely than
13 not, that's what would occur, Your Honor, or my belief.

14 **Q.** Let's go to the next slide. This is Cardinal Health.
15 Of the 92,915 transactions, which admittedly go into a
16 longer data time frame than the other defendants, how many
17 suspicious orders were you able to find in the record
18 between 1996 and 2012 -- 2011?

19 **A.** 0.

20 **Q.** Well, that's not true, is it, Mr. Rafalski?

21 **A.** Oh, I think that's changed. I'm sorry. For 2010 would
22 be the first order that was discovered.

23 **Q.** So, between -- in 1996, how many suspicious orders were
24 reported?

25 **A.** 0 up through 19 -- 2009.

1 Q. And then in 2010, how many were reported?

2 A. 1.

3 Q. And how about 2012?

4 A. 2012, 115.

5 Q. I'm sorry. I missed 2011.

6 A. 2011, 0.

7 Q. And then, beginning in 2012, how many suspicious orders
8 were reported?

9 A. 15 for 2012; 86 for 2013; 5 for --

10 THE COURT: Did you say 15 for 2012?

11 THE WITNESS: 115, Your Honor. I'm sorry. Again,
12 86 for 2013; 5 for 2014; 19 for 2015; 34 for 2016; 32 for
13 2017.

14 Q. So, just for purposes of the record, between 1996 and
15 2011, Cardinal Health reported one suspicious order?

16 A. That's correct, Your Honor.

17 Q. Now, let's go to the next slide, please. And, again,
18 this is McKesson and of the 18,862 transactions, how many
19 suspicious orders were reported by McKesson from 1996
20 through 2012?

21 A. That would be 0, Your Honor.

22 Q. And then beginning in 2013, how many suspicious orders
23 were reported?

24 A. Five orders in 2013; 29 orders in 2014; 20 orders in
25 2015; 10 orders in 2016; 2 in 2017; and 13 in 2018, Your

1 Honor.

2 **Q.** Now, with regard to Rite Aid, McKesson's relationship
3 with Rite Aid, did you find any evidence in the record that
4 McKesson conducted sufficient due diligence of the Rite Aid
5 stores in Huntington-Cabell County, West Virginia?

6 **A.** I did not, Your Honor.

7 **Q.** Did you find any evidence that McKesson conducted
8 sufficient due diligence when increasing thresholds of
9 hydrocodone and oxycodone for Rite Aid stores in
10 Huntington-Cabell County, West Virginia?

11 **A.** Your Honor, I did not.

12 **Q.** And did you find any evidence that McKesson was
13 sufficiently monitoring Rite Aid's self-distribution of
14 hydrocodone to its stores in Huntington-Cabell County, West
15 Virginia?

16 MR. SCHMIDT: Objection, Your Honor. Based on an
17 implied legal duty that doesn't exist, we can't monitor
18 someone's independent conduct from us.

19 THE COURT: Well, overruled.

20 Go ahead, Mr. Farrell.

21 THE WITNESS: No, they didn't, Your Honor.

22 BY MR. FARRELL:

23 **Q.** And did you find sufficient evidence of an appropriate
24 Level I or Level II review by McKesson for retail national
25 account customers in Huntington-Cabell County, West

1 Virginia?

2 **A.** I did not, Your Honor.

3 **Q.** Mr. Rafalski, do you have an opinion whether
4 AmerisourceBergen maintained effective control to prevent
5 diversion of prescription opioids into the illicit market in
6 Huntington-Cabell County, West Virginia?

7 **A.** Yes, Your Honor, I do.

8 **Q.** What is that opinion?

9 **A.** Failure to maintain effective controls to prevent
10 diversion of controlled substances.

11 MR. NICHOLAS: Your Honor, I'll object and ask to
12 strike that testimony as a legal conclusion.

13 THE COURT: Well, overruled.

14 BY MR. FARRELL:

15 **Q.** So, let's back up. Do you have an opinion and I'll --
16 I'm going to use the collective to save us some time.

17 THE COURT: Overrule the objection and deny the
18 motion to strike.

19 Go ahead, Mr. Farrell.

20 BY MR. FARRELL:

21 **Q.** Do you have an opinion whether AmerisourceBergen
22 maintained effective control to prevent diversion of
23 prescription opioids into the illicit market in
24 Huntington-Cabell County, West Virginia?

25 **A.** I do.

1 Q. What is that opinion?

2 A. That they did, Your Honor.

3 Q. Do you have an opinion whether Cardinal Health
4 maintained effective control to prevent diversion of
5 prescription opioids into the illicit market in
6 Huntington-Cabell County, West Virginia?

7 MS. MAINIGI: Objection, Your Honor. Calls for a
8 legal conclusion inconsistent with the Geldhof ruling.

9 THE WITNESS: I do, Your Honor.

10 BY MR. FARRELL:

11 Q. What is that opinion?

12 A. That they did.

13 Q. That they did not?

14 A. They did not. I'm sorry. Yes.

15 Q. Do you have an opinion whether McKesson maintained
16 effective control to prevent diversion of prescription
17 opioids into the illicit market in Huntington-Cabell County,
18 West Virginia?

19 MR. SCHMIDT: Same objection, Your Honor.

20 THE COURT: Overruled.

21 THE WITNESS: I do, Your Honor.

22 BY MR. FARRELL:

23 Q. What is that opinion?

24 A. That they did not.

25 Q. Do you have an opinion whether AmerisourceBergen,

1 Cardinal Health and McKesson each individually designed and
2 operated an effective system to identify, block and report
3 suspicious orders arising out of Huntington-Cabell County,
4 West Virginia?

5 **A.** I do, Your Honor.

6 **Q.** And what is that opinion?

7 **A.** That they did not.

8 **Q.** Do you have an opinion whether these failures were
9 systemic?

10 **A.** I do, Your Honor.

11 **Q.** And what is your opinion?

12 **A.** That they were.

13 **Q.** Do you have an opinion --

14 THE COURT: What do you mean by systemic failure?

15 THE WITNESS: Systemic would -- the difference
16 would be when I looked at the due diligence, maybe there was
17 a flaw or a missed one. Systemic would mean that it was
18 widespread, that it was --

19 THE COURT: Okay. Ms. Mainigi?

20 MS. MAINIGI: I object to that, Your Honor. He
21 has absolutely no basis in terms of what he reviewed to do
22 that and ultimately it calls for a legal conclusion but we
23 can cross examine him on it.

24 THE COURT: Overruled.

25 MR. FARRELL: All right. I'm being told that I

1 need to -- because of the objections and the clarity, I need
2 to go back and re-ask the first question on
3 AmerisourceBergen.

4 BY MR. FARRELL:

5 **Q.** You've stated earlier that you do -- let me start all
6 over with that. Do you have an opinion whether
7 AmerisourceBergen maintained effective control to prevent
8 diversion of prescription opioids into the illicit market in
9 Cabell County, West Virginia?

10 **A.** I do, Your Honor.

11 **Q.** And what is your opinion?

12 **A.** They did not.

13 THE COURT: Haven't you already asked him that?

14 MR. FARRELL: I was told that I --

15 THE COURT: Oh, you wanted to rephrase the
16 question?

17 MR. FARRELL: I was told I bollixed it and so I
18 was trying to fix it.

19 THE WITNESS: I might have misunderstood it, Your
20 Honor.

21 THE COURT: Okay. All right. I'm sorry. Go
22 ahead.

23 BY MR. FARRELL:

24 **Q.** Do you have an opinion whether these systemic failures
25 were a substantial factor in the diversion of prescription

1 Statement." Do you see that? It's immediately below in the
2 upper left corner.

3 **A.** I do see that under "Action," yes, sir.

4 **Q.** This is the kind of DEA policy statement specifically
5 relating to prescription opioids that we were just
6 referencing; correct?

7 **A.** Generally, yes. I think this is a proposal for
8 multiple prescriptions for Schedule II. But I agree that's
9 what the policy statement says.

10 MR. SCHMIDT: We move this into evidence,
11 Defendants' West Virginia 3076.

12 THE COURT: Is there any objection?

13 MR. FARRELL: Yes, Your Honor.

14 THE COURT: What is it?

15 MR. FARRELL: Well, this is hearsay, and unless
16 this Court takes judicial notice of a public document. But
17 in addition to that, there's been no foundation that this
18 witness is familiar with this policy statement from the DEA.

19 MR. SCHMIDT: I don't think the witness -- an
20 expert witness gets to decide the scope of his cross
21 examination by a limited review of documents. There is
22 foundation that this is the type of document he would look
23 at.

24 THE COURT: This comes in under the public records
25 exception to the hearsay rule, does it not?

1 MR. SCHMIDT: Yes.

2 THE COURT: Objection is overruled. I'll admit
3 it.

4 BY MR. SCHMIDT:

5 Q. Okay. Let's put it up on the screen, please. And
6 we don't need to go back through the background
7 information.

8 What I want to do is go to Page 5 of the document
9 looking at the numbers in the lower left-hand corner,
10 please. And tell me when you're there. And we also have it
11 up on the screen. It's just to your right. Do you see
12 that?

13 A. Yes. One second.

14 Q. And, specifically, if we cull out the right column,
15 there's a heading that says, "The number of physicians who
16 prescribe controlled substances in violation of the CSA is
17 extremely small and there is no DEA crack-down on
18 physicians."

19 Do you see that?

20 A. I see what that says, yes.

21 Q. And then it says in 2006 in the Federal Register in
22 this official DEA policy statement, DEA recognizes that the
23 overwhelming majority of American physicians who prescribe
24 controlled substances do so for legitimate medical purposes.

25 Do you disagree with that statement?

1 **A.** I do not.

2 **Q.** You agree with that?

3 **A.** Yes, Your Honor, I agree with that.

4 **Q.** In fact, the overwhelming majority of physicians who
5 prescribe controlled substances do so in a legitimate manner
6 that will never warrant scrutiny by federal or state law
7 enforcement officials.

8 Do you agree with that?

9 **A.** Your Honor, I do agree with that statement, too.

10 **Q.** Do you recall when you were at the DEA that the head of
11 the Office of Diversion Control was Joseph Rannazzisi?

12 **A.** I do, sir.

13 **Q.** And you're aware that he has publicly stated under oath
14 in testimony that 99 point -- 99 percent of doctors
15 prescribe opioids for legitimate medical purposes? You and
16 I have looked at that testimony together. Correct?

17 **A.** Your Honor, we have and I do recall that testimony.

18 **Q.** And you agree with that testimony; correct?

19 **A.** Yes.

20 **Q.** You're aware that the former head of the DEA, Robert
21 Patterson, has similarly testified under oath to our United
22 States Congress that 99.99 percent of doctors are trying to
23 do right by their patients?

24 **A.** I do not recall that testimony, hearing that testimony
25 before, Your Honor.

1 **Q.** I've shown you that testimony. Do you recall that?

2 **A.** I do not. 99.99? I do not.

3 **Q.** Well, do you agree -- let me ask it this way. Do you
4 agree with the statement made by Mr. Patterson of the DEA,
5 formerly of the DEA testifying in front of Congress that
6 99.99 percent of doctors are trying to do the right thing?

7 Do you agree or disagree with that statement?

8 **A.** It's a difficult decision, Your Honor, because I'm
9 thinking about the approximately one million physicians in
10 the United States and calculating what one tenth of
11 one percent would be. I guess generally I don't have any
12 information to disagree with it.

13 **Q.** Okay.

14 **A.** I'm not, I'm not as certain when you bring it down to
15 one tenth of one percent.

16 **Q.** Okay. No reason to disagree with it?

17 **A.** No, I don't have any information to disagree other than
18 my experience in working with the DEA might taint my opinion
19 a little bit because I -- you know, prior to that, I didn't
20 have the same contact with physicians that were having
21 problems with dispensing and all other issues. But other
22 than that, I do not, Mr. Schmidt.

23 **Q.** You agree that the medical community bears some
24 responsibility for the opioid crisis; correct?

25 **A.** Your Honor, I believe that probably everybody bears

1 some responsibility for the opioid crisis. I, I don't think
2 that anyone can sit here today that took a role in trying to
3 combat it would ever say they did everything perfectly.

4 **Q.** Does that include the DEA?

5 **A.** That includes the DEA.

6 **Q.** Does that include Joe Rannazzisi, former head of the
7 Office of Diversion Control of the DEA?

8 **A.** I guess Mr. Rannazzisi would speak for himself.

9 **Q.** I'm asking your view, sir.

10 **A.** I, I've already stated I think everybody, if they were
11 able to look back and look at what they did, I don't think
12 there's anybody in America that could say, "I did everything
13 perfect."

14 **Q.** Does that include Mr. Rannazzisi in your view?

15 **A.** If I make a statement like that, I guess I would hope
16 that he could look back and feel the same way.

17 **Q.** Now, I'll come back to my question and ask you about
18 doctors. Do doctors -- do you agree that doctors bear some
19 responsibility for the opioid crisis?

20 **A.** I believe they do.

21 **Q.** You're testifying here as a DEA expert; correct?

22 **A.** I don't know if I'm a DEA expert. I'm not employed
23 anymore. I'm an expert, I guess, with a DEA background.

24 **Q.** Okay. I don't want to split hairs. You've come here
25 as an expert on DEA topics as a former employee of the DEA;

1 correct?

2 **A.** Yes. I just didn't want to be a DEA expert.

3 **Q.** Are you aware of the DEA's 360 programs?

4 **A.** Not in great detail. It was something that was
5 starting right around my retirement. I think it wasn't
6 really fully rolled out until after I left in 2017.

7 **Q.** Okay. Have you had occasion to look at the DEA's 360
8 program covering Cabell County in connection with your work
9 in this case?

10 **A.** I have not, Your Honor.

11 **Q.** Do you know what causes the DEA has identified through
12 their 360 project as causes of the opioid crisis in Cabell
13 County?

14 **A.** No, I do not.

15 **Q.** That's not something you've looked at in your work?

16 **A.** I believe that I may have looked at a document or some
17 information regarding that. I don't have a direct
18 recollection and I don't want to guess on that topic, Your
19 Honor.

20 MR. SCHMIDT: May I approach, Your Honor?

21 BY MR. SCHMIDT:

22 **Q.** I've handed you a document marked Defendants' West
23 Virginia 2628. Do you see on the cover it says "DEA 360
24 Strategy"?

25 **A.** I see that, Your Honor.

1 Q. And if you look at Page 7 of the document --

2 A. Okay.

3 Q. -- do you see that it covers Cabell, among other
4 counties?

5 A. I see that, sir.

6 Q. It was launched in February, 2017. Do you see that?

7 A. I do.

8 Q. And it covers Cabell County; correct?

9 A. That's a correct statement, sir.

10 Q. Do you see on Page 9 that they have a chart with
11 factors contributing to the opioid problem in West Virginia?

12 A. I see that page, yeah, Your Honor.

13 Q. And do you see under that the third factor is
14 over-prescribing of opioids? Do you see that?

15 A. I agree that that is what that statement says.

16 Q. Do you agree that's a factor contributing to the opioid
17 problem in West Virginia, doctors over-prescribing opioids?

18 A. I think that's a logical statement that there would be
19 some over-prescribing or prescribing issues that would lead
20 to that issue.

21 Q. Do you see they have data and they cite someone named
22 Dr. Gupta who this Court has heard from already?

23 MR. FARRELL: Can you give me a page number?

24 MR. SCHMIDT: Oh, yes, of course. I might have
25 read the wrong one, Page 9. It's 4 on the document. But if

1 you look at the lower numbers, those are the numbers I'm
2 going to be using all through the document.

3 BY MR. SCHMIDT:

4 **Q.** Do you take any issue with the data cited here
5 regarding prescribers over-prescribing opioids in West
6 Virginia coming from the DEA and from Dr. Gupta?

7 **A.** Your Honor, I don't have any problems with the data. I
8 don't have any independent knowledge, or I haven't done any
9 research or looked up, you know, to be able to give an
10 informed comment on that. I don't have any reason to not
11 believe the data, sir.

12 **Q.** Do you see that there's discussion in this DEA 360
13 publication citing Dr. Gupta, citing the DEA, citing the
14 National Institute on Drug Abuse talking about factors
15 contributing to the opioid problem in West Virginia? There
16 is no mention of distributors?

17 **A.** There is not, Your Honor, at least on the two pages
18 we've reviewed so far.

19 MR. SCHMIDT: We'll move this into evidence, Your
20 Honor, Defendants' West Virginia 2628.

21 MR. FARRELL: Objection; hearsay, foundation, and
22 geographic scope.

23 THE COURT: How does it come in, Mr. Schmidt?

24 MR. SCHMIDT: I think it's an official record, and
25 it's certainly a record of the type experts use and would

1 rely on under 703.

2 THE COURT: Well, they can consider it under 703.
3 That doesn't necessarily make it admissible under 703. Is
4 there an exception to the hearsay rule?

5 MR. SCHMIDT: I think it's a government
6 publication.

7 BY MR. SCHMIDT:

8 **Q.** Is this a document you reviewed before, Mr.
9 Rafalski?

10 **A.** I've never seen this before, sir.

11 **Q.** Okay.

12 MR. SCHMIDT: I won't move it in, then, Your
13 Honor.

14 THE COURT: All right.

15 BY MR. SCHMIDT:

16 **Q.** In terms of Cabell County and Huntington, you don't
17 know how many doctors in Cabell/Huntington -- Cabell
18 County and Huntington who wrote prescriptions for
19 opioids during the time period you were looking at in
20 this case; correct?

21 **A.** Your Honor, I did not research that topic, so I do not
22 know.

23 **Q.** So it follows that you conducted no analysis of how
24 many doctors were prescribing legitimately in
25 Huntington/Cabell versus illegitimately. True?

1 **A.** I did not conduct any research on that and I did not
2 look into that matter. So I do not have an opinion on it.

3 **Q.** I'm trying to get you off today, so I'm going to ask
4 you if you can answer just my question. I'm just going to
5 try to ask "yes/no" questions where I can.

6 **A.** Okay. Your Honor, when I can answer "yes/no" I will.

7 THE COURT: Okay. And you can explain your answer
8 when you desire to do so.

9 THE WITNESS: I understand, Your Honor.

10 BY MR. SCHMIDT:

11 **Q.** Your report and your testimony doesn't identify a
12 single doctor who you have identified in Cabell County
13 or Huntington who was prescribing improperly or engaging
14 in diversion. True?

15 **A.** That's correct.

16 **Q.** You talked about Dr. Ognen, a pill mill doctor you
17 investigated in -- was it Michigan?

18 **A.** Toledo, Ohio, sir.

19 **Q.** In Toledo, Ohio, during your work at the DEA. Do you
20 recall that?

21 **A.** I do.

22 **Q.** You didn't conduct that type of investigation of any
23 doctors in Huntington or Cabell as part of your work in this
24 case; correct?

25 **A.** I was not requested to do that type of analysis, Your

1 Honor.

2 **Q.** So did you do it?

3 **A.** I did not.

4 **Q.** Okay. You've not done any kind of analysis of the
5 medical needs for prescription opioids in Cabell County or
6 Huntington relative to the national average; correct?

7 **A.** That's a correct statement. I did not do that.

8 **Q.** So it follows that you can't identify a single instance
9 where an order from McKesson or ABDC or Cardinal went to
10 fill a prescription written by a doctor in Cabell County or
11 Huntington where the doctor was prescribing improperly or
12 engaging in diversion. True?

13 **A.** I don't think that's a true statement.

14 **Q.** Which doctors had prescriptions filled by one of these
15 defendants that was acting improperly or engaging in
16 diversion?

17 **A.** Well, I'm aware of an incident through reviewing of
18 records, doing some research on some of the records for some
19 of the pharmacies that there was a, a pharmacy located in
20 Huntington that was filling prescriptions for the whole pain
21 clinic.

22 **Q.** Okay.

23 **A.** And all 12 of the people involved with the whole pain
24 clinic were all indicted.

25 During the time frame that those doctors were

1 prescribing, they were filling prescriptions. There was a
2 pharmacy or pharmacies in this area filling prescriptions
3 for them.

4 Now, I don't have any independent knowledge to say
5 those specific prescriptions. But based on the totality of
6 all the circumstances, I would say it's likely that there
7 were prescriptions issued that were illicit during that time
8 period.

9 **Q.** Do you know of any pills shipped by McKesson, ABDC, or
10 Cardinal that specifically went to a pill mill doctor or an
11 improper prescription?

12 **A.** As I just testified, I think in this case it's likely.
13 I think the pharmacy I recall being was a customer of
14 McKesson.

15 **Q.** Do you know if that happened?

16 **A.** The distribution?

17 **Q.** Yes, the distribution of pills -- you just mentioned
18 McKesson -- by McKesson that went to fill a prescription
19 that was written by a pill mill doctor?

20 **A.** I don't know that they filled that specific
21 prescription. I just know they went to the pharmacy.

22 **Q.** What was that McKesson customer?

23 **A.** I'm drawing a blank on it.

24 **Q.** It's no one you mentioned in your report; correct?

25 **A.** It's not in my report, no, sir.

1 Q. It's no one you mentioned in your testimony; correct?

2 A. Not so far, that's correct.

3 Q. And you realize we're done with your affirmative
4 testimony from Mr. Farrell; correct?

5 A. I am.

6 Q. Okay. In a similar vein, are you aware of any pills
7 that were shipped by McKesson, ABDC, or Cardinal that ended
8 up filling a prescription that was dispensed other than in
9 response to a licensed prescriber writing a prescription?

10 A. No, I'm not, Your Honor.

11 Q. Let's talk about pharmacies. Pharmacies dispense
12 prescription opioids in response to prescriptions; correct?

13 A. That's correct, sir.

14 Q. And the DEA registers the pharmacies, and the West
15 Virginia Board of Pharmacy licenses the pharmacies in West
16 Virginia; correct?

17 A. That's correct.

18 Q. And both of those, that registration, that licensing
19 are both important; correct?

20 A. Yes. It's required by law.

21 Q. You're not aware of Cardinal, ABDC, or McKesson ever
22 supplying a pharmacy that was not licensed by the DEA?

23 A. I do not, Your Honor.

24 Q. You understand that under DEA rules when you were at
25 the DEA and to this day that pharmacies have a corresponding

1 responsibility to that of the doctor when it comes to
2 prescriptions?

3 **A.** Yes, but, more specifically, the pharmacist.

4 **Q.** The pharmacist?

5 **A.** Not the pharmacy.

6 **Q.** What is that corresponding responsibility that a
7 pharmacist has?

8 **A.** They're supposed to ensure that that prescription was
9 issued for a legitimate medical need and, if necessary, that
10 there was a proper doctor/patient relationship.

11 If while filling the prescription they identify any
12 anomalies or red flags, they have an obligation to resolve
13 those before issuing the prescription.

14 **Q.** And that language, that corresponding responsibility is
15 written into the regulation; correct?

16 **A.** It is a regulation, sir.

17 **Q.** There's no reference to a corresponding responsibility
18 of distributors, correct, in the regulation?

19 **A.** There is not.

20 **Q.** So is it accurate to say that pharmacies have
21 meaningful responsibilities when it comes to prescription
22 opioids?

23 **A.** Yes, but, more specifically, pharmacists.

24 **Q.** Are you aware of any prescription in this case relating
25 to the defendants that was dispensed without a pharmacist

1 present with that pharmacist having that corresponding
2 responsibility?

3 **A.** I am not, Your Honor. That was not part of what I did
4 research for for my report.

5 **Q.** And it's because of that corresponding responsibility
6 that pharmacists have that at the DEA they're often referred
7 to as the last line of defense against diversion; correct?

8 **A.** I've never heard that specific term about pharmacists
9 but --

10 **Q.** Okay.

11 **A.** -- I don't dispute that that could be a term used.

12 **Q.** You never heard that in your work at DEA?

13 **A.** No, I did not.

14 **Q.** Okay.

15 **A.** I, I heard that used for other entities in the closed
16 system, but not for pharmacists.

17 **Q.** A pharmacy can't dispense a prescription opioid without
18 having a prescription from a licensed healthcare prescriber
19 and properly evaluating it. True?

20 **A.** Could you say the end again? I'm sorry.

21 **Q.** Sure. A pharmacy can't dispense prescription opioids
22 without having a prescription in hand from a licensed
23 healthcare professional and properly evaluating it.

24 Correct?

25 **A.** Generally speaking. There's some emergency provisions,

1 Your Honor, where the prescription can follow-up within a
2 certain time frame. So that's part of having it in hand.
3 But, basically, that's a true statement, Your Honor.

4 **Q.** All right. And that statement is true no matter how
5 many prescription opioids are distributed; correct?

6 **A.** That's correct.

7 **Q.** The number of pills that a pharmacy dispenses are
8 directed by the number of prescriptions written by
9 healthcare professionals. True?

10 **A.** Generally speaking, yes.

11 **Q.** You don't know how many pharmacies dispensed
12 prescription opioids during the time period you were looking
13 at in Cabell County and Huntington; correct?

14 **A.** I don't know them off of my -- off the top of my head,
15 but I do have a chart where I have for the three defendants
16 the number of pharmacies. The totality of all the
17 pharmacies, if there were ones that were receiving
18 controlled substances outside of the three defendants, I
19 would not have those. So --

20 **Q.** You weren't -- you weren't tasked with evaluating the
21 pharmacies in Cabell County and Huntington in terms of
22 whether they were complying with their legal obligations;
23 correct?

24 **A.** That's correct, Your Honor. I wasn't evaluating
25 pharmacies.

1 **Q.** You weren't asked to review specific pharmacy records,
2 how the records were maintained, whether they were
3 dispensed, whether their corresponding responsibility was
4 fulfilled by the pharmacists; correct?

5 **A.** That's a correct statement, Mr. Schmidt.

6 **Q.** So you did not undertake those reviews; correct?

7 **A.** I did not, Your Honor.

8 **Q.** Correspondingly, you do not know of any pharmacies in
9 Cabell County or Huntington -- let me actually ask you a
10 different question. You're not offering any opinions about
11 whether diversion occurred at a pharmacy level; correct?

12 **A.** I haven't put that opinion in my report, so I guess
13 that's a true statement, Your Honor.

14 **Q.** You understand that some of the large pharmacy chains
15 act as distributors themselves by self-distributing to
16 themselves; correct?

17 **A.** There's -- it's a possibility for a pharmacy, but
18 there's a rule, a percent rule of how much they can do that.

19 **Q.** With respect, I didn't ask you -- I just asked you if
20 it's correct. Is it correct that some chain pharmacies
21 self-distribute?

22 **A.** General knowledge, I know that. As far as within
23 Cabell County and Huntington, I don't have any knowledge of
24 that occurring.

25 **Q.** Do you know of any pharmacy, chain pharmacy in

1 Huntington or Cabell County that self-distributes?

2 **A.** No, I do not.

3 **Q.** Okay. Some of the pharmacies that are large chains are
4 pharmacies like CVS, Walgreens, Rite-Aid; correct?

5 **A.** Yes.

6 **Q.** And you know they self-distribute in other locations;
7 correct?

8 **A.** I know I've seen things where they might transfer
9 controlled substances back and forth to each other, which is
10 permissible.

11 **Q.** This is now, by my count, the fifth case where you're
12 giving opinions against various defendants, is that correct,
13 regarding prescription opioids?

14 **A.** Yes.

15 **Q.** In other cases you've given the opinions that those
16 chain pharmacies I mentioned have caused the opioid crisis;
17 correct?

18 **A.** Yes.

19 **Q.** In fact, you're going to leave this court and go to
20 give a deposition in another case where you're giving the
21 opinion that those chain pharmacies in another jurisdiction
22 have caused the opioid crisis; correct?

23 **A.** That's correct.

24 **Q.** You know that they had stores in Huntington/Cabell;
25 correct?

1 Q. Dated April 15th, 2019?

2 A. Yes, sir.

3 Q. And do you see item 4 right above your signature,
4 "Deposition testimony by current Insys employees has
5 confirmed that Insys failed to implement any SOMS system or
6 maintain any SOMS protocols until 2018."

7 Do you see that?

8 A. I see that, Your Honor.

9 Q. Were you being truthful when you provided that report,
10 sir?

11 A. I was. I just didn't recall it, sir.

12 Q. Let me ask you now about distributors. Distributors
13 ship medications from the manufacturers that make them to
14 pharmacies and other entities that dispense them; correct?

15 A. Yes, any registrant that has the ability to purchase
16 them, yes, sir.

17 Q. In doing that, distributors play an important role in
18 ensuring an adequate and uninterrupted supply of legitimate
19 prescription opioids; correct?

20 A. I believe that's the role -- one of the roles of a
21 distributor, yes, sir.

22 Q. They don't fill prescriptions brought to them. That's
23 the role of the pharmacy. Correct?

24 A. That's correct, Your Honor.

25 Q. They don't check the prescriptions that patients bring

1 into a pharmacy; correct?

2 **A.** That's a correct statement.

3 **Q.** In fact, they don't have access to individual patient
4 prescriptions or individual patient data; correct?

5 **A.** That's a correct statement.

6 **Q.** Privacy laws actually prevent that; correct?

7 **A.** HIPAA requirements would prohibit that, sir.

8 **Q.** Those are privacy laws; right?

9 **A.** Yes, they are.

10 **Q.** So distributors don't have the information to evaluate
11 the medical need of an individual patient presenting an
12 individual prescription; correct?

13 **A.** That's a correct statement, Your Honor, they do not.

14 **Q.** You're not aware of any instance where one of the three
15 distributors in this case directly interacted with a doctor
16 or a patient in Huntington or Cabell County, are you?

17 **A.** I'm not aware if that occurred, sir.

18 **Q.** Let me ask you a question about the relationship
19 between pharmacies and distributors. You're aware that when
20 a distributor cuts off a customer, it's common that that
21 pharmacy will go find another distributor to supply its
22 pills; right?

23 **A.** That's true, yes, sir.

24 **Q.** In fact, in your work experience you're aware of no
25 instance ever when a pharmacy has cut off -- I'm sorry -- a

1 distributor has cut off a pharmacy and that pharmacy has
2 gone out of business because they can't find another
3 distributor; correct?

4 **A.** No, I'm not, not immediately.

5 **Q.** What does cut off a pharmacy is if the DEA pulls the
6 pharmacist's registration -- or I'm sorry -- the pharmacy's
7 registration; correct?

8 **A.** Yes. If the DEA or the state was to remove the
9 licensure from the pharmacy, they would stop immediately.

10 **Q.** You agree that there are hundreds of distributors in
11 the United States?

12 **A.** Yes.

13 **Q.** And you agree from reviewing Dr. McCann's data that
14 dozens of distributors supply pharmacies in Huntington and
15 Cabell?

16 **A.** Dozens? I think that may be a little high, but I
17 don't, I don't have any direct recollection to dispute that.

18 **Q.** Dr. McCann testified it was 36. Is that accurate?

19 **A.** If he testified, then that's accurate.

20 **Q.** Okay. And that's two and a half dozen; right?

21 **A.** Yes.

22 **Q.** You conducted no analysis of the distributors that
23 shipped into Huntington and Cabell County other than
24 McKesson, Cardinal, and ABDC; correct?

25 **A.** That's correct, Your Honor. Those are the only three I

1 reviewed.

2 **Q.** To take one example of the distributors you failed to
3 address, the distributor Miami-Luken had a high level of
4 conduct in West Virginia; correct?

5 **A.** I'm aware that they were distributing also into the
6 county and the city at considerable amounts, Your Honor.

7 **Q.** Do they still exist?

8 **A.** I believe they do. I think they have some legal
9 matters pending, but I think they still have their
10 registration.

11 **Q.** What are those legal matters pending?

12 **A.** I believe there are some criminal charges pending
13 against the company.

14 **Q.** And you did no analysis of Miami-Luken's efforts to
15 prevent diversion and comply with the CSA; correct?

16 **A.** I was not asked to do that. No, Your Honor, I did not.

17 **Q.** Did you look at a pharmacy called A-Plus Pharmacy in
18 your work?

19 **A.** In Cabell and Huntington?

20 **Q.** Yes. It was a Miami-Luken pharmacy.

21 **A.** I believe so.

22 **Q.** Do you know that -- then you know that ABDC, Cardinal,
23 and McKesson never supplied A-Plus Pharmacy?

24 **A.** I'm not sure on that, sir.

25 **Q.** Well, did you see in Dr. McCann's data that they never

1 answers on the application can fraudulently obtain a DEA
2 registration."

3 Do you see that?

4 **A.** I see it.

5 **Q.** Do you have any reason to question the truth of that as
6 to registration decisions made for Huntington/Cabell?

7 **A.** I do not.

8 **Q.** Let's look at the last sentence.

9 "Indeed, one diversion investigator told us that even
10 if an applicant answered "yes" to one or more of the
11 liability questions, some of her colleagues do not follow up
12 to determine whether the applicant should be denied a DEA
13 registration."

14 Do you see that?

15 MR. FARRELL: Objection, Your Honor.

16 THE COURT: What's the basis?

17 MR. FARRELL: Hearsay within hearsay.

18 MR. SCHMIDT: It's a report --

19 THE COURT: Well, this is cross-examination. He
20 can answer it if he can.

21 BY MR. SCHMIDT:

22 **Q.** Do you see that?

23 **A.** Yes, sir, I do see that. Is this restricted to Cabell
24 County and Huntington?

25 **Q.** I haven't asked a question. I just asked if you saw

1 it.

2 **A.** Oh, okay. I'm sorry.

3 **Q.** Do you have any reason to take issue with the truth of
4 that statement as applied to registration in
5 Huntington/Cabell?

6 **A.** I do not, sir.

7 **Q.** Do you know the DEA can use ARCOS data to determine the
8 volume of opioids supplied by all distributors to a
9 pharmacy; correct?

10 **A.** I do.

11 **Q.** They can use ARCOS data to determine the volume of
12 opioids supplied by all distributors to a county; correct?

13 **A.** I'm sorry? To a --

14 **Q.** To a county.

15 **A.** Yes.

16 **Q.** You've seen this document that we have marked as
17 Defendants' West Virginia 642; correct?

18 **A.** It looks familiar. I'm not positive.

19 **Q.** We had a chance to talk about it in your New York
20 deposition; correct?

21 **A.** I believe so.

22 **Q.** You'll remember we actually took a break from your
23 deposition so you could go and confirm on the DEA website
24 that this is, in fact, a publication available on the DEA
25 website talking about the ARCOS database; correct?

1 **A.** I recall it except I think one of the attorneys for the
2 defendants actually found it but, yes.

3 **Q.** Yes. One of my colleagues in this room found it and
4 pointed you to it and you were able to confirm that this is
5 from the DEA's website?

6 **A.** Yes. And then I was willing to discuss it, yes, sir.

7 MR. SCHMIDT: We move this into evidence, Your
8 Honor.

9 THE COURT: Any objection?

10 MR. FARRELL: Just a second, Your Honor.

11 (Pause)

12 BY MR. SCHMIDT:

13 **Q.** And to lay just a further foundation, you've read
14 the testimony of Kyle Wright as taken in the broader
15 opioids litigation; correct?

16 **A.** Yes, sir.

17 **Q.** And this is an exhibit to his deposition because it
18 was, in fact, a presentation he conducted; correct?

19 **A.** Yes.

20 MR. FARRELL: No objection, Your Honor.

21 THE COURT: It's admitted.

22 BY MR. SCHMIDT:

23 **Q.** Let's put this up on the board. It says "ARCOS
24 Automation of Reports and Consolidated Order System."
25 This is this ARCOS database we've been talking about;

1 THE COURT: Do you know why DEA did not permit
2 disclosure before 2018?

3 THE WITNESS: For a while, Your Honor, they used
4 to say it was proprietary. But then I, I think also they
5 felt there, there was input from distributors and
6 manufacturers, that they would use the data as a tool to go
7 in and try to see what market share was and then try to
8 take -- fight each other on, you know, where they knew that
9 they could market a product and where it was being
10 distributed. I think there was that visibility that was a
11 problem.

12 BY MR. SCHMIDT:

13 Q. They were forced to overcome those concerns and
14 grant access; correct?

15 A. I think the opioid epidemic helped them overcome those
16 concerns.

17 Q. An act of Congress helped them overcome those concerns;
18 right?

19 A. Yes.

20 Q. The DEA failed to act in that regard; correct?

21 A. I'm not sure what guidance they had to take that
22 position, but they did not act. That's an accurate
23 statement.

24 Q. Let's go back to 21, please. Do you remember talking
25 about how the DEA had the ability to look at a county by

1 county basis and determine whether that county was average,
2 above average, below average?

3 **A.** I do.

4 **Q.** Are you aware of the DEA ever looking at City of
5 Huntington or Cabell County and telling any distributor the
6 level of distribution to that county was wrong?

7 **A.** I'm not aware whether that did or did not occur, Your
8 Honor.

9 **Q.** You were asked a question about whether distributors
10 ever analyzed volume to a specific county. Did DEA, to your
11 knowledge, ever look at the overall distribution or any one
12 distributor's distribution to Huntington or Cabell County
13 and make a judgment that it should be different?

14 **A.** Not that I'm aware of, Your Honor.

15 **Q.** Was any such judgment ever communicated to any
16 distributor in this case?

17 **A.** Not that I'm aware of, Your Honor.

18 **Q.** I want to go back to the quotas for opioids that we
19 touched on earlier. And let's go back -- do you still have
20 that Office of the Inspector General report in front of you?

21 **A.** I do.

22 **Q.** Exhibit DEF-WV-1597, please. And if you could start by
23 looking at Page 7 of that document. I'm sorry, Page 12 of
24 that document, again looking at the numbers in the bottom
25 right-hand corner.

1 If you look at the numbered paragraphs, I want to ask
2 you a question about that Paragraph Number 1, please.

3 Do you see that in Number 1 they're discussing the APQ,
4 aggregate production quota or, as they refer to it in the
5 first clause, the national quota? Do you see that?

6 **A.** I do.

7 **Q.** I want to look at the second sentence if we could and
8 ask you if you have this understanding of what quota is.

9 Quote: "The maximum amounts of each basic class of
10 Schedule I and II controlled substances the DEA
11 administrator deems necessary for manufacture in a calendar
12 year by all pharmaceutical manufacturers combined."

13 And this is the part I want you to focus on:

14 "For the estimated medical, scientific, research, and
15 industrial needs of the United States or for lawful export."

16 Is that your understanding of how the quota is supposed
17 to be set?

18 **A.** I do. That is my understanding, Your Honor.

19 **Q.** And, specifically, is it your understanding that the
20 quota is supposed to be based on estimated medical need and
21 other delineated needs?

22 **A.** Yes, Your Honor, that's the criteria.

23 **Q.** Should citizens be able to rely on the DEA
24 appropriately setting quota based on medical and other
25 listed needs? Yes or no?

1 **A.** Yes, Your Honor.

2 **Q.** Let's look at Page 18, please.

3 You're aware the DEA has been faulted for not meeting
4 that trust that has been given to it in terms of setting the
5 quota; correct?

6 **A.** I'm, I'm aware that they've been criticized for their
7 handling of the quota, yes, sir.

8 **Q.** Let's look at Page 18, please.

9 Do you see that -- if we cull out the first paragraph,
10 please.

11 In the second sentence it talks about the rising opioid
12 overdose death rate. Do you see that?

13 **A.** I do.

14 **Q.** And then in the next sentence it says, "Yet, from 2003
15 to 2013, DEA authorized manufacturers to produce substantial
16 amounts of opioids."

17 And then it gives an example. "For example, the
18 aggregate production quota, APQ, of oxycodone in the U.S.
19 increased over 400 percent from 34,482 kilograms in 2002 to
20 a high of 153,750 kilograms in 2013."

21 Do you see that?

22 **A.** I do.

23 **Q.** And you're aware that that's factually true?

24 **A.** I don't dispute it. I, I don't know that that's, you
25 know, a, a factual statement. I don't have any reason to

1 not believe it either, Your Honor.

2 **Q.** And if we look at the next page, it actually shows us
3 the amount by which the quota has gone up. Do you see that?

4 **A.** I do.

5 **Q.** As the plaintiffs' diversion control investigations
6 expert in this case, do you take any issue with the numbers
7 in this report regarding the DEA's quota?

8 **A.** I think it bears some scrutiny, but I wasn't present
9 when they -- I don't know what material they reviewed. I
10 don't know how those decisions were made. I know we
11 discussed it before.

12 I, I have some concerns about just whacking the quota.
13 I think that's what it was called for for a period of time.
14 But, obviously, with the opioid epidemic raging, I'm not
15 sure raising it is, was the most prudent. But it's
16 difficult for me to give you an opinion when I wasn't
17 actually involved with that decision-making, Mr. Schmidt.

18 **Q.** All I was asking you was do you take issue with these
19 numbers?

20 **A.** I do not.

21 **Q.** Okay. Let's look back at the page we were looking at,
22 Page 18.

23 **A.** Okay.

24 **Q.** In the second paragraph it says, "However, it was not
25 until 2017 that then acting DEA administrator Chuck

1 Rosenberg reduced the APQ for most controlled substances,
2 including oxycodone, by 25 percent."

3 Do you see that?

4 **A.** I do.

5 **Q.** And if we look at the next page, you can see that
6 illustrated graphically. Do you see that?

7 **A.** I do.

8 **Q.** Do you take any issue with the factual accuracy of
9 that?

10 **A.** I do not.

11 **Q.** Now, maybe you touched on this in that other answer.
12 Was it a good thing that the DEA reduced the quota?

13 **A.** I think it's a good thing as long as they monitor to
14 make sure that cutting the quota didn't deprive people who
15 legitimately needed the medication to receive it.

16 And I say that because if you can start to diminish the
17 diversion, then it's okay to cut the quota. But just
18 cutting the quota and there's a problem in America, you
19 know, one of the unintended consequences is always a concern
20 that people that need drugs don't get them.

21 **Q.** Okay. If you impose arbitrary limits, you might impact
22 diversion, but you might also keep it from people who need
23 it; correct?

24 **A.** That's, that's my point, yes, sir.

25 **Q.** And that's true at the DEA; correct?

1 **A.** I just think that --

2 **Q.** In terms of their quota. I'm sorry.

3 **A.** Pardon me?

4 **Q.** In terms of their quota.

5 **A.** I just think it's -- I think it's a by-product of
6 taking an act without realizing what the consequences are.
7 You know, it's -- if depriving people who need opioids
8 legitimately so that there's less diversion, I, I -- you
9 know, that's a decision that people way above where I was in
10 the DEA made, but it's a concern to me because, you know,
11 they're important medications for some people.

12 **Q.** That would be a concern for distributors too. If they
13 arbitrarily imposed limits on prescription opioids, that
14 could also deprive medication from people who needed it.
15 True?

16 **A.** I hope it's a concern for everyone. I hope there's not
17 somebody that would say, "I don't want people to be able to
18 obtain medication."

19 **Q.** Is what I said true, sir?

20 **A.** Yeah, it's true.

21 **Q.** Thank you. If we look at the heading -- let's go back
22 to 17.

23 Just -- not less than two years ago, the heading on
24 this page, the OIG was concluding DEA was slow to respond to
25 the dramatic increase in opioid abuse and needs to more

1 MR. SCHMIDT: Thank you.

2 THE COURT: It's admitted.

3 MR. SCHMIDT: Let's go ahead and put it up on the
4 screen. If we could go to the second page of the document,
5 please.

6 BY MR. SCHMIDT:

7 Q. Do you see it's got a heading called "Where the
8 Drugs Come From"?

9 A. I do.

10 Q. And the last sentence of that paragraph says, "More
11 than three out of four people who misuse prescription
12 painkillers use drugs prescribed to someone else."

13 Do you see that?

14 A. Yes.

15 Q. Do you take any issue with that, with that statistic?

16 A. No, I do not. That's I think a little different than
17 the previous one. I think the previous one was more
18 directed at family members and friends.

19 Q. You agree that when a prescription is legitimately
20 written and dispensed, distributors have no control over
21 what happens to it after that point?

22 A. That's a correct statement. I agree with that, Your
23 Honor.

24 THE COURT: We probably ought to take a break when
25 you get to a stopping point. Is this a good place?

1 MR. SCHMIDT: This is that point, Your Honor.

2 THE COURT: All right. Let's be in recess for 10
3 minutes.

4 (Recess taken at 3:12 p.m.)

5 THE COURT: You may resume, Mr. Schmidt.

6 MR. SCHMIDT: Thank you.

7 BY MR. SCHMIDT:

8 Q. Mr. Rafalski, let me pick up where we were. Do you
9 have in front of you the CDC publication MCWV-2096?

10 A. I do, sir.

11 Q. Let me just go back to Page 7. I'm told I read it into
12 the record wrong. Is the statistic they provide on Page 7
13 the following: Quote, more than three out of four people
14 who misuse prescription pain-killers use drugs prescribed to
15 someone else? Is that the quote?

16 A. Yes.

17 Q. And you take no issue with that?

18 A. I do not.

19 Q. All right. I want to come to your flagging
20 methodologies. And before I come to your flagging
21 methodologies, I'm just going to ask you general questions
22 about the obligations that distributors have; fair?

23 A. Yes.

24 Q. Distributors have a duty to report all their sales to
25 the DEA for the DEA's ARCOS database, correct?

1 **A.** All the ARCOS required drugs.

2 **Q.** Yes. And you agree that ARCOS uniquely has access to
3 all of the data submitted by each DEA registrant across the
4 country?

5 **A.** I'd agree with that, Your Honor.

6 **Q.** ARCOS is compiled by DEA in accordance with law,
7 correct?

8 **A.** Yes, sir.

9 **Q.** It's used for developing quota?

10 **A.** That's correct, Your Honor.

11 **Q.** It's used for analyzing distribution trends?

12 **A.** That's correct a statement, Your Honor.

13 **Q.** It's used for internal audits?

14 **A.** Internal audits?

15 **Q.** Yes, sir.

16 **A.** Can you define that a little further for me?

17 **Q.** Sure.

18 MR. SCHMIDT: Could we put up the expert report
19 from Mr. Rafalski in this case, P-42216, just for
20 demonstrative purposes, and go to Page 17? P-42216, please.
21 Now -- this is the wrong tab. It should be Tab 18. There
22 we go. Could we look at Page 17, please? And could we cull
23 out the second paragraph, please?

24 BY MR. SCHMIDT:

25 **Q.** This is what I was reading to you from, sir. Do you

1 see that it states the ARCOS DADS system uniquely has access
2 to all of the data submitted by each DEA registrant across
3 the country?

4 **A.** I see that paragraph and I see what part you're
5 speaking of, yes, sir.

6 **Q.** And then it says the data is compiled by DEA in
7 accordance with law. Do you see that?

8 **A.** I see that statement.

9 **Q.** Is that accurate?

10 **A.** Yes, sir.

11 **Q.** DEA uses it for inspections, correct?

12 **A.** Yes.

13 **Q.** They use it for investigations, correct?

14 **A.** That's correct.

15 **Q.** And they use it for other analyses, as well, correct?

16 **A.** That's correct.

17 **Q.** You're aware that Dr. McCann confirmed through his work
18 that the distributors in this case reported all of their
19 sales into DEA's ARCOS database, all of their required
20 sales, between 2006 and 2014?

21 **A.** Except, I believe, there was a gap of data, I believe,
22 for Cardinal for a short period of time.

23 **Q.** Okay. And did you see his testimony where he explained
24 that that could have been due to a recordkeeping issue on
25 the DEA side?

1 **A.** Yes. I'm just trying to answer your question
2 accurately, sir.

3 **Q.** And you don't take any issue with Dr. McCann's
4 conclusion that the ARCOS data received from the defendants
5 in this case is reliable, do you?

6 **A.** I do not take an exception to that, Your Honor.

7 **Q.** Distributors also have a duty to report suspicious
8 orders to the DEA, correct?

9 **A.** Yes, sir, when discovered.

10 **Q.** And let's -- let's take a look at that definition. I
11 think this is a regulation, so I think the Court can take
12 notice of it without me moving it in as an exhibit.

13 So, if I may just put it up on the screen, please.
14 It's DEF-WV- 2254. And this is the regulation as quoted
15 from the DEA website.

16 And if we could just cull out A paragraph. Actually,
17 that's the wrong paragraph. I'm sorry.

18 THE COURT: Is there any objection to me taking
19 judicial notice of this, Mr. Farrell?

20 MR. FARRELL: Not that I can think of.

21 MR. SCHMIDT: Let's cull up Paragraph B, please.

22 THE COURT: Well, I want to give you the
23 opportunity.

24 MR. FARRELL: This is -- this is -- this is the
25 CFR, correct?

1 MR. SCHMIDT: Yes.

2 THE COURT: It's judicially noticed.

3 BY MR. SCHMIDT:

4 Q. And do you see it defines suspicious orders and the
5 last sentence here is orders of unusual size, orders
6 deviating substantially from a normal pattern, and orders of
7 unusual frequency? Do you recognize that as the regulatory
8 definition of a suspicious order?

9 A. That's what the regulation says, yes, sir.

10 Q. Are you aware that this -- how long has this regulation
11 been in place?

12 A. 1971, Your Honor.

13 Q. Are you aware that just in the last year the DEA has
14 proposed amending this regulation?

15 A. I am.

16 Q. Are you aware that the subject of the proposed DEA
17 amendment is including in the regulation a do not ship
18 requirement?

19 A. I am.

20 Q. Are you aware that another subject of the proposed
21 amendment is including in the text of the regulation
22 provisions regarding recordkeeping?

23 A. I'm aware of that, also.

24 Q. There's no express reference in this definition of a
25 suspicious order to likely diversion, is there?

1 **A.** Well, it's my belief, Your Honor, the word suspicious
2 is suspicious of the diversion, although I do agree with Mr.
3 Schmidt it does not say that, but it's what it's suspicious
4 of.

5 **Q.** And that's -- that phrase you just used, suspicious of
6 diversion, that phrase appears nowhere in here?

7 **A.** That's correct.

8 **Q.** Instead, it refers to orders of unusual size,
9 frequency, pattern, correct?

10 **A.** I think that qualifies some of the things that -- that
11 may define it.

12 **Q.** And you're aware that there are all kinds of
13 circumstances when an order can be of unusual size, pattern
14 or frequency, but not be diverted?

15 **A.** That's a correct statement. I agree with that, Your
16 Honor.

17 **Q.** One example of that is a pharmacy might have a Cancer
18 Center open nearby and suddenly they have an unusual
19 pattern, orders of unusual size, or orders of an unusual
20 frequency, right?

21 **A.** That's correct.

22 **Q.** That could show up as a suspicious order even though
23 none of them are being diverted, correct?

24 **A.** Ultimately, if due diligence was done, that would be a
25 conclusion that a distributor could come to, that's correct.

1 **Q.** Another example, a pharmacy could be across the street
2 from another pharmacy that closes and so, all of that closed
3 pharmacy's customers start coming to the pharmacy that's
4 still open, correct?

5 **A.** Yes. That's another scenario, although that -- that
6 also has some potential issues that would have to be
7 resolved, but I don't disagree with that statement.

8 **Q.** And all I'm asking you, sir, is that can be an instance
9 where an order looks like it has unusual size, frequency or
10 pattern, but there's no diversion, correct?

11 **A.** That's a possibility, yes, sir.

12 **Q.** And do you have any idea, have you seen any studies
13 that tell us how many of the orders that meet this
14 definition are actually diverted?

15 **A.** Well, I know there's a comment in the new proposed
16 rule. Other than that, I've never seen anything that gave
17 an approximation.

18 **Q.** Do you know if you take the body of suspicious orders
19 that have occurred over time how many of them are actually
20 diverted?

21 **A.** I don't know that, no, sir. I don't know that, Your
22 Honor.

23 **Q.** Do you know if it's above or below five percent, ten
24 percent?

25 **A.** I don't know, Your Honor.

1 **Q.** Let me focus on some of the numbers that you showed the
2 Court. I tried to count the numbers of Suspicious Order
3 Reports you identified in your 2007-2008 time period and I
4 got 416 from all three defendants. Does that sound right?

5 **A.** Yes, sir.

6 **Q.** Including 79 from McKesson?

7 **A.** That's correct.

8 **Q.** And that's even though you didn't count any DU45s for
9 McKesson from before 2007, correct?

10 **A.** That's correct.

11 **Q.** Can you -- whether it's those pre-2007 orders or any of
12 the orders you identified, can you point to any action DEA
13 took on any suspicious order that McKesson, Cardinal or ABDC
14 made for Cabell County or Huntington?

15 **A.** I cannot, Your Honor.

16 **Q.** You're not aware of any Suspicious Order Reports
17 regarding pharmacies in Huntington or Cabell that led to any
18 investigation by DEA, correct?

19 **A.** I am not, Your Honor, although I didn't review or look
20 to determine that, but I'm not independently aware of that.

21 **Q.** You can't point me to any orders that any one of these
22 three defendants shipped into Huntington or Cabell where the
23 DEA came to them and said you should not have shipped that
24 specific order, correct?

25 **A.** That's a true statement. I didn't -- do not know that,

1 Your Honor.

2 **Q.** Are you aware that since 2007 and 2008, ABDC, Cardinal
3 and McKesson have blocked orders that go above specific
4 thresholds?

5 **A.** I'm aware of that, those changes upon that time period,
6 yes, sir.

7 **Q.** How many have they blocked?

8 **A.** I don't recall.

9 **Q.** Do you recognize it's hundreds of thousands nationwide?

10 **A.** I didn't look at nationwide.

11 MR. FARRELL: Objection, Your Honor, geographic
12 scope.

13 THE COURT: Overruled.

14 THE WITNESS: I do not know, Mr. Schmidt.

15 BY MR. SCHMIDT:

16 **Q.** Do you know how many it is in West Virginia?

17 MR. FARRELL: Objection, Your Honor, on the same
18 basis.

19 THE COURT: Overruled.

20 THE WITNESS: I do not.

21 BY MR. SCHMIDT:

22 **Q.** Do you know how many it is in Huntington-Cabell?

23 **A.** In the totality, I do not.

24 **Q.** You would agree that if you block an order, that
25 obviously keeps it from being distributed and it would not

1 lead to diversion, correct?

2 **A.** Say one more time. I'm sorry.

3 **Q.** If you block an order, that would obviously keep it
4 from being distributed and it would not lead to diversion?

5 **A.** That's a correct statement, Your Honor. I agree with
6 that.

7 **Q.** Blocking the order of opioid pills before shipment is
8 what prevents diversion from occurring, correct?

9 **A.** Yes, Your Honor, that's what prevents it.

10 **Q.** You'd agree that not reporting the suspicious order to
11 DEA is not what causes diversion, correct?

12 **A.** That -- I agree with that statement, Your Honor.

13 **Q.** Now, let's talk about your flagging methodologies.
14 You've performed them -- you showed some pretty big numbers
15 in those methodologies; do you remember that?

16 **A.** Yes, I remember. There were big numbers.

17 **Q.** Some of them were 80-90 percent, correct?

18 **A.** That's correct.

19 **Q.** You've performed those across various jurisdictions,
20 correct?

21 **A.** I performed them for Cabell County and for Huntington,
22 City of Huntington. Is that your question?

23 **Q.** No. And for Cuyahoga County. And for Summit County.

24 **A.** Oh.

25 **Q.** And for Nassau County. And for Suffolk County. And

1 for two counties in the State of Iowa; correct?

2 **A.** That's -- that's accurate. I thought we were talking
3 --

4 MR. FARRELL: Objection, Your Honor. Objection,
5 Your Honor, compound.

6 THE COURT: Sustained. You can break it up.

7 BY MR. SCHMIDT:

8 **Q.** You performed it for Cuyahoga County?

9 **A.** I did.

10 **Q.** You performed it for Summit County?

11 **A.** I did, Your Honor.

12 **Q.** You performed it for Nassau County?

13 **A.** I did, Your Honor.

14 **Q.** Performed it for Suffolk County?

15 **A.** Yes, I did, Your Honor.

16 **Q.** You performed it for two counties in the State of Ohio
17 where you're going to go give testimony in two weeks
18 regarding pharmacies?

19 **A.** That's correct, Your Honor.

20 **Q.** And every one of those analyses, you always get similar
21 numbers to what you get here, right?

22 **A.** They're high numbers. I don't -- I don't remember -- I
23 don't recall if they're -- how close they are to being
24 similar, but they're all high numbers. I agree with that
25 statement.

1 Q. You didn't look at any of them at the time you wrote
2 your expert report and adopted them; correct?

3 A. That's correct.

4 Q. Not one of the initial orders; not one of the follow-up
5 orders; correct?

6 A. That's correct. I'm sorry. I didn't know that was a
7 question.

8 Q. And you -- as an illustration of that, you haven't
9 looked at which pharmacies generate the most flagged orders
10 under your methodology, correct?

11 A. At the time we talked before, I didn't, we didn't, but
12 I've since went back and reviewed all of the triggers, so --

13 Q. Okay. Do you know which pharmacy triggered the least
14 orders under your method?

15 A. Not as I sit here. I didn't memorize and recite them,
16 but I did look and see which ones triggered and -- how quick
17 they triggered and the amounts they triggered based on our
18 previous conversations.

19 Q. Where did Rite Aids fit in the picture? Were they the
20 most? Were they the least? Were they somewhere in between?

21 COURT REPORTER: I'm sorry. Can you slow down
22 just a little for me?

23 MR. SCHMIDT: Yes. I'm sorry.

24 COURT REPORTER: Were they the most --

25 MR. SCHMIDT: Actually, I'll withdraw the

1 question.

2 BY MR. SCHMIDT:

3 **Q.** None of that is in your report? None of that was in
4 your opinions before the Court today, correct?

5 **A.** That's correct.

6 **Q.** And you performed no analysis in your report or in your
7 opinions today of whether pharmacies that took more or less
8 care to meet their corresponding responsibility had more or
9 less flagged orders, correct?

10 **A.** That's -- I made no correlation between the
11 pharmacists' corresponding responsibility and the flagged
12 orders, Your Honor.

13 **Q.** This is a long one. I apologize for that. I wrote no
14 correlation with corresponding responsibilities. In terms
15 of these orders that you claim were likely diverted, you
16 don't know how many of those orders went to fill legitimate
17 medical need, correct?

18 **A.** I do not, Your Honor.

19 **Q.** You don't know whether it's 99 percent of the flagged
20 orders that went to legitimate medical need, 1 percent, or
21 some other number?

22 **A.** I do not know, Your Honor.

23 **Q.** So, the results of your methodologies are not based on
24 any estimate of medical need, correct?

25 **A.** That's correct. It doesn't include a basis for a -- or

1 a requirement for medical need.

2 **Q.** And I believe you said in your direct examination at
3 one point that 90 percent of the pills should not have been
4 shipped. Do you remember saying something to that effect?

5 **A.** Yes. Based on the assumption, that's correct.

6 **Q.** Now, if that view were followed, how many cancer
7 patients would have been deprived of medication?

8 **A.** Well --

9 **Q.** How many, sir, do you know?

10 **A.** So, what I report to the judge, what I report to you,
11 Your Honor, is -- is more likely than not how many of those
12 pills could have the potential for diversion because the
13 first order didn't have a due diligence inspection or didn't
14 dispel the diversion.

15 It's not saying that none of those 90 percent would
16 actually have been distributed because they actually were
17 when there was no due diligence. What I'm saying is the
18 likeliness of the potential of diversion is based on the
19 fact that that first order wasn't clear and that that
20 suspicion of diversion is present.

21 **MR. SCHMIDT:** Your Honor, may I ask the witness to
22 answer my question now?

23 **THE COURT:** Yeah. Yeah. The question was how
24 many, wasn't it?

25 **BY MR. SCHMIDT:**

1 **Q.** Yeah. Do you know how many?

2 **A.** I do not, Your Honor.

3 **Q.** Do you know how many patients recovering from surgery
4 would be deprived of medication if your opinions were
5 followed?

6 **A.** I do not.

7 **Q.** Do you know how many patients receiving end of life
8 care would be deprived of medications if your opinions were
9 followed?

10 **A.** Your Honor, I do not.

11 **Q.** Do you know how many doctor prescriptions for
12 legitimate medical need would not be filled if your opinions
13 were followed?

14 **A.** I do not, Your Honor.

15 **Q.** And so, I take it you have not done a specific
16 assessment if you haven't looked at the orders and you've
17 not looked at which ones were based on medical need and
18 you've not done an assessment of whether specific flagged
19 orders led to specific harm; true?

20 **A.** That's a correct statement, Your Honor.

21 **Q.** So, I'll write not based on harm. Now, I want to get
22 at this point in another way and I think what I'd like to do
23 is if I can show you some of those demonstratives that you
24 looked at with Mr. Farrell.

25 MR. SCHMIDT: Do I need to switch the screen

1 around? This is fraught with possibility for disaster, but
2 okay. Could we put Slide 17 and Slide 18 up next to each
3 other, please?

4 BY MR. SCHMIDT:

5 Q. You talked about having six different methods. This is
6 just two of them, Method A, Method B, and those are going to
7 be the ones I'm going to focus on most of all for reasons
8 we'll talk about.

9 A. Okay.

10 Q. I want to just give two illustrations. You did Method
11 A and Method B for oxycodone for McKesson, correct?

12 A. Yes.

13 Q. And using Method A, you get 87.9 percent. Do you see
14 that?

15 A. Yes.

16 Q. Using Method B, you get 22.2 percent. Do you see that?

17 A. I do.

18 Q. Pretty big difference, right?

19 A. That's a big difference.

20 Q. 87.9 percent is over 400 percent times this estimate of
21 20.2 percent, correct?

22 A. It is.

23 Q. Which of those two is the right number?

24 A. I believe that the larger one is.

25 Q. Okay. We'll talk about the difference between those

1 **A.** Yes.

2 **Q.** And counties, correct?

3 **A.** That's correct.

4 **Q.** Have you gone to any of your clients and said you
5 should use this to make your registration decisions for
6 pharmacies, or distributors, or your re-registration
7 decisions?

8 **A.** I have not done that, but I have not been asked either,
9 Your Honor. I haven't approached anyone to try to tell them
10 to do that.

11 **Q.** Has anyone in the world that you know of adopted the
12 stylized illustrations that you have presented to the Court
13 in this case?

14 **A.** I have no knowledge that anyone has used these based on
15 my publications in the -- in my report that's now open to
16 the public.

17 **Q.** Okay. So, it's been open to the public and no one has
18 used it, correct?

19 **A.** Not that I'm aware of. I said I'm not aware if anyone
20 has.

21 **Q.** Let's go back to your slide presentation, please, and
22 if we could cull up Page 14 of your slide presentation.
23 This is your list of the six methodologies, correct?

24 **A.** That's correct, Your Honor.

25 **Q.** Let's go through a few of them. Am I correct that when

1 it comes to methodologies, C through F, you have not used
2 those methods?

3 **A.** Well, it wouldn't be up to me to use or not. If -- if
4 you're asking me -- if he's asking me, Your Honor, would I
5 -- if someone was to come to me and say should I use these
6 methodologies, I'm not a DEA person anymore. I would tell
7 them no and I would give them reasons why.

8 **Q.** Let me try it one more time. You would not use methods
9 C through F, correct?

10 **A.** If I owned a company, a distributor, and I was going to
11 design a suspicious order system, that's the basis for your
12 question, that's correct, I would not use those.

13 **Q.** Let's focus on these other two. You say Masters here.
14 Do you see that?

15 **A.** Yes.

16 **Q.** That's a reference to the Masters decision, right?

17 **A.** That's correct.

18 **Q.** You don't say Masters here, correct?

19 **A.** Only probably because it didn't fit on the slide, but
20 it's -- it's also a Masters.

21 **Q.** It's also a Masters? That's where I was going,
22 correct?

23 **A.** Yes. It just treats it different with removing the
24 assumption.

25 **Q.** And you acknowledge that Method A differs from Masters

1 in important regards, correct?

2 **A.** Yes.

3 **Q.** Let's talk about that. And before I do, I'm going to
4 talk about both Method A and Method B. This case is the
5 first of your several cases where you've used these
6 methodologies that you used Method B; is that right?

7 **A.** That's correct.

8 **Q.** And you adopted Method B after we had the chance to
9 critique the way Method A was conducted in your other cases,
10 correct?

11 **A.** That's part of the reason, Your Honor, in depositions,
12 questions in depositions, to take a look at it a different
13 way.

14 **Q.** Okay. Let's talk about that so the Court is on the
15 same page as us. Method A and Method B are the same
16 generally except that Method A uses what you refer to as a
17 due diligence assumption and Method B does not, correct?

18 **A.** That's correct.

19 **Q.** And that's what explains that chasm between the two
20 numbers, 87 percent and 20 percent, right?

21 **A.** Yes. More specifically, A differs from B because B --
22 the assumption in B is, is that a suspicious order is
23 identified but yet, the shipping continues. The only
24 difference is it's fixed after the first triggered threshold
25 and that's done for a different reason.

1 Q. Okay. And I'm going to dig into that but, first, I
2 just want to add to this point we've been discussing.

3 New methodology following criticism. I want to talk
4 about that difference, that due diligence assumption. When
5 Dr. McCann ran Method A for you, the way he ran Method A was
6 by using the assumption that distributors did not conduct
7 any diligence on the first flagged suspicious order,
8 correct?

9 A. That's correct.

10 Q. And so, what that means is anytime a first order gets
11 flagged, everything else gets flagged, correct?

12 A. That's correct for each pharmacy.

13 Q. And you have not looked at those initial orders for
14 McKesson, Cardinal and ABDC that are the initial flagged
15 orders under your Method A, correct?

16 A. Could you -- could you ask that a little further and
17 rephrase it? I'm --

18 Q. Sure. Of course, I can.

19 A. -- not sure I understand.

20 Q. I'll ask it just -- just the way we've talked about it
21 before. Have you looked at those initial orders for
22 McKesson, Cardinal and ABDC that are the initial flagged
23 orders of your Method A?

24 A. I have not, Your Honor.

25 Q. Did you individually review any of them to see if you

1 just looked at the order on its face whether you would
2 consider it to be suspicious?

3 **A.** I did not, Your Honor.

4 **Q.** Did you review the diligence files for every one of
5 these tens of millions of flagged orders?

6 **A.** Some, I would say, yes.

7 **Q.** It wouldn't be possible to review all of them, though,
8 and you did not review all of them, correct?

9 **A.** That's correct. I -- I reviewed the files of the
10 defendants, so if -- and I believe those files were past the
11 trigger date. So, I would have reviewed some of the files.

12 **Q.** Okay. You don't know how many of the orders initially
13 flagged under your methodologies were actually investigated
14 and determined not to be suspicious, correct?

15 **A.** Based on the systemic failure, I guess I couldn't rule
16 out possibility that one of them or two of them were
17 investigated, Your Honor, but just based on my review, there
18 was very little to no due diligence investigations, so I
19 would say I wouldn't have to review that to have an opinion
20 on that.

21 **Q.** Can we cull up the September 11th, 2020 transcript at
22 Page 99, Lines 9-17? And do you see I asked you, do you
23 know of those initial flagged orders under Method A how many
24 between 0 and 100 percent were actually investigated and the
25 flag cleared by the defendants? Answer, I don't have a

1 definitive answer to that, sir. Okay. That's not something
2 you tried to evaluate, correct? Answer, I did not. Did I
3 read that correctly?

4 **A.** You did.

5 **Q.** Were you being truthful in giving that testimony?

6 **A.** I was.

7 **Q.** And, in fact, you don't have a number as to how many of
8 these tens of millions of orders should have been reported
9 to the DEA as suspicious, correct?

10 **A.** Well, in Methodology A, if the due diligence is not --
11 the -- the suspicion is not dispelled, there's no due
12 diligence, then every order after that first order.

13 **Q.** Can we look at the September 11th, 2020 transcript at
14 Page 102, please, on Line 20-23? Do you see where I asked
15 you how many of these tens of millions of orders should have
16 been reported to the DEA as suspicious? Do you see that?

17 **A.** I do. And I believe that's a different question than
18 you asked me.

19 **Q.** Okay. What's the answer to how many of these -- the
20 record will say what it says. Let me finish my impeachment
21 and then we can move on. The answer is, I don't have a
22 number, sir. Do you see that?

23 **A.** I would agree with that statement.

24 **Q.** So, in case we misunderstood each other, let me just
25 ask you. Do you know how many of these tens of millions of

1 orders should have been reported to the DEA as suspicious?

2 **A.** No, I do not.

3 **Q.** For shorthand, I'm going to write don't know how many
4 reportable.

5 So, let's go back to this -- this difference between
6 Method A and Method B and I want to illustrate for the
7 Court, if I could, how it works --

8 **A.** Sure.

9 **Q.** -- in terms of that initial order gets flagged and
10 everything after gets flagged, okay?

11 **A.** Sure.

12 **Q.** And do you recall that in his report, Dr. McCann gives
13 an illustration, and I just don't remember if you copied it
14 into your report, but he gives an illustration of a pharmacy
15 where, in a six-month period, you had 5,000, and then
16 10,000, and then 7,000, and 8,000, and 9,000, and 9,500
17 pills. Do you remember that illustration? I can show it to
18 you, if you would like.

19 **A.** I generally recall it. I do not believe it's in my
20 report.

21 MR. SCHMIDT: Okay. So, let's -- if we could put
22 up McKesson Demonstrative 2, please, just for illustration.
23 Do I need to switch the screen?

24 So, we have tried to replicate that example. It's
25 probably going to be covered by that offense. There we go.

1 Q. And it's only been for the past couple of years,
2 correct?

3 A. I believe I've only read one report based on that law.

4 Q. And you recall that we've had the chance to do math
5 together on that and calculate that for the past couple
6 years for oxycodone and hydrocodone and the DEA's
7 calculations are less than .1 percent diversion using their
8 method, correct?

9 A. Yes. And I believe that I didn't agree with that.

10 Q. You've done the type of calculation of actual diversion
11 that the DEA has conducted, correct?

12 A. I have not. I just draw -- I make that statement just
13 based on the pure number.

14 Q. You've never published your estimates, your flagging
15 methods, with a source like the Federal Register as you know
16 the DEA has?

17 A. I have not, Your Honor.

18 Q. And you're not aware of anyone who has tried to conduct
19 the same types of calculations of actual diversion that the
20 DEA has conducted, which show less than .1 percent diversion
21 and come up with different numbers, are you?

22 A. I am not.

23 Q. Okay. I'm going to change gears now and this will
24 probably take us through the day. Starting in 2007 and
25 2008, are you aware that McKesson, ABDC and Cardinal began

1 automatically blocking orders that exceed thresholds?

2 **A.** I am. All of them develop new programs in that time
3 frame and all of them included a block of orders.

4 **Q.** You can't point me to any company before 2007 that
5 blocked every order that went over a threshold or that it
6 reported to the DEA, correct?

7 **A.** As I sit here, I'm not aware of one, but I can't say
8 that one didn't exist, Your Honor.

9 **Q.** And do you know of a prior public occasion when the DEA
10 said any order you identify as suspicious should not be
11 shipped prior to this 2007 window we're talking about?

12 **A.** In those exact terms, Your Honor, that's -- I do not
13 know of that.

14 **Q.** DEA never specifically told McKesson, ABDC or Cardinal
15 not to ship an order identified as suspicious before that
16 time period, correct?

17 **A.** Not in those exact terms, although I think there's been
18 discussions where they talk about the maintenance of
19 effective controls to prevent diversion, and they talk about
20 identifying a suspicious order, and they talk about
21 companies having a liability or a responsibility for public
22 interest. So, I think if you put that together, it says
23 that, but to actually -- if I understand the correction to
24 say do not ship, no, I am not aware that they've said that
25 in that way.

1 **Q.** Before 2007, DEA never took action against the company
2 because they reported orders, but did not block them,
3 correct?

4 **A.** I don't want to split hairs. Southwood might have been
5 in 2006, but --

6 **Q.** Southwood was 2007, sir. If you want to look back at
7 your slide with it on it, I can refresh you. Why don't we
8 put that up?

9 **A.** I think that may be the ruling, but I think the action
10 -- action might have been sooner, but I'm not disputing the
11 2007.

12 **Q.** Okay.

13 **A.** I don't want to argue about a year.

14 **Q.** And you, yourself, acknowledged that there was no do
15 not ship requirement before 2007 when you were a DEA agent,
16 correct?

17 **A.** I -- I recall that I was testifying. We've discussed
18 it before and I was asked and I believe I said it was a
19 change in policy.

20 **Q.** In this 2007 time frame, correct?

21 **A.** I don't remember the exact time frame. I think it was
22 just in reference to -- I don't remember if I testified in
23 reference to the distributor briefings or the Rannazzisi
24 letters.

25 **Q.** Okay. Those all happened in the 2006-2007 time frame,

1 correct?

2 **A.** Well, the distributor briefings were in '05.

3 **Q.** They started in early January 2006 and went into 2007
4 according to your testimony, correct?

5 **A.** The distributor briefings?

6 **Q.** The distributor initiative?

7 **A.** I believe they occurred for the defendants in '5 and
8 '6.

9 **Q.** Okay. Well, whatever year we're talking about in that
10 window, you testified that before that time the DEA never
11 told distributors not to ship orders they were reporting,
12 correct?

13 **A.** I don't know if I testified to those exact words. I do
14 recall that, when questioned about it, I said it was a
15 change in policy and that was based on some information that
16 was provided me by another diversion investigator.

17 **Q.** Okay. Let me ask you about the context where this
18 testimony came up. You were involved in a case called
19 *United States v. \$463,497.72*. Do you remember that?

20 **A.** Yes, sir.

21 **Q.** You were actually the chief investigator in that case,
22 correct?

23 **A.** I was.

24 **Q.** And you were deposed in that case?

25 **A.** That's where I made the statement, sir.

1 Q. And you testified at trial in that case?

2 A. I didn't testify to that at trial, but I did at the
3 deposition, yes, sir.

4 Q. In that case, you testified that distributors were
5 first told about the do not ship requirement as part of the
6 distributor initiative, correct?

7 A. I believe -- I believe that's a true statement. I
8 think that that's the first time the DEA made a more
9 definitive statement do not ship.

10 Q. And you said -- I'm sorry.

11 A. No, go ahead.

12 Q. You said those distributors briefings began in January,
13 2006, correct?

14 A. If that's what I testified to, looking at -- now
15 looking at some of the distributor briefings as part of my
16 review of records in this case, I see that they were in
17 2005.

18 Q. And that's since you've been hired as a plaintiffs
19 expert and given documents by plaintiffs' attorneys,
20 correct? True?

21 A. Well, yes, looking at discovery material, that's
22 correct.

23 Q. I want to focus on what you were doing when you were
24 severing the United States Government as a diversion
25 investigator. At that time, you said distributor briefing

1 started in January, 2006, correct?

2 **A.** If I made that statement, then that's what I believed
3 at that time and it would have been provided to me by
4 another diversion investigator, not actually looking at the
5 documents of the briefing.

6 **Q.** And you testified that the do not ship requirement is
7 not contained in the regulations or the statutes, correct?

8 **A.** The actual words do not ship do not appear anywhere in
9 the statute or in the regulations.

10 **Q.** And you said that they were only informed of it by the
11 DEA in these distributor briefings, correct?

12 **A.** I was aware they were informed of it then, yes, sir.

13 **Q.** There was a published court decision based on your
14 testimony, correct?

15 **A.** Yes, there was, Your Honor.

16 **Q.** And you read that decision when it came out?

17 **A.** I did.

18 **Q.** You testified in that case, before the judge in that
19 case?

20 **A.** I did, Your Honor.

21 **Q.** And your colleagues testified in that case, before the
22 judge in that case?

23 **A.** Yes, other diversion investigators, if you mean that,
24 yes, sir.

25 **Q.** That is what I mean, sir.

1 **A.** Yes, sir.

2 **Q.** You had the chance to sit there and hear them testify?

3 **A.** I did sit there. I was the officer in charge of the
4 investigation, Your Honor. I watched all their testimony.

5 **Q.** Because you were the chief investigator in this case,
6 correct?

7 **A.** I was.

8 **Q.** Do you recognize what I've marked as DEF-WV-2661 as the
9 case where you testified and where you were, in fact, the
10 chief investigator?

11 **A.** I do recognize this, Your Honor.

12 MR. SCHMIDT: Your Honor, again, we don't think
13 it's appropriate to move a case into evidence, but I do
14 think it's relevant, and the Court can take judicial notice
15 of it. So, absent objection, I will put it up on the
16 screen.

17 THE COURT: All right.

18 MR. SCHMIDT: Let's go to Page 5 of this decision.
19 And can we cull out the first paragraph under (f)? It
20 states -- the second sentence there states the regulations
21 do not prescribe any particular form or style of monitoring
22 system. Do you see that?

23 **A.** I do see it and I believe that's an accurate statement.

24 **Q.** Got me on my next question. Thank you. Let's go to
25 Page 6, please, and if we could cull out the third and the

1 Q. And do you know that they're talking about the do not
2 ship requirement there?

3 A. I believe that's what they're referring to.

4 Q. And they say that change in policy apparently prompted
5 concern within the DEA compliance sectors that confusion
6 would result since the prior report only, that's the
7 opposite of blocking, right? Yes?

8 A. Yes. Yes. I'm sorry. I didn't know you were done. I
9 didn't know you were done speaking. I'm sorry.

10 Q. That change in policy apparently prompted concern
11 within the DEA compliance sectors that confusion would
12 result since the prior report-only policy had been in place
13 for 35 years. Do you see that?

14 A. That's what this says, yes, sir.

15 Q. Therefore, DEA personnel began to conduct distributor
16 briefings to familiarize drug wholesalers with the new
17 policy. Do you see that?

18 A. That's what it says, Your Honor.

19 Q. And that's the distributor briefings we've been talking
20 about in '06 and '07, correct?

21 A. Yes, it is.

22 Q. And then there's reference to Kyle Wright conducting
23 one of those distributor briefings, correct?

24 A. That's correct.

25 Q. And I think you might have been involved in some later,

1 but you were not involved in any during that time period,
2 correct?

3 **A.** I went and actually watched a distributor briefing.
4 Didn't participate other than to observe it in the Fall of
5 2008.

6 **Q.** And then, let's look down in the next paragraph. In
7 all events, Wright -- that's a reference to Kyle Wright, one
8 of your colleagues at DEA, right?

9 **A.** Yes.

10 **Q.** Wright testified that the DEA was aware that it was
11 standard practice in the industry to file Suspicious Order
12 Reports while continuing to ship products. Do you see that?

13 **A.** I see that.

14 **Q.** And you are aware that Agent Wright gave that
15 testimony, right? You watched him give it?

16 **A.** I'm aware of it, Your Honor.

17 **Q.** It goes on to say and that practice had been approved
18 by the DEA. You're aware he gave that testimony, correct?

19 **A.** I'm aware he did.

20 **Q.** You watched him give it, correct?

21 **A.** I did.

22 **Q.** And as the chief investigator on this case, you never
23 stood up to disagree with him, correct?

24 **A.** I did not.

25 **Q.** Let's go to Page 6, please, of the opinion. I guess

1 we're actually on Page 6, further down, second paragraph
2 from the bottom. Mentions another one of your colleagues in
3 this second sentence. Do you know who Michael Mapes is?

4 **A.** I do.

5 **Q.** Also one of your colleagues at DEA?

6 **A.** He was also employed at the DEA. I guess he would be a
7 colleague. To me, that infers there's some kind of like a
8 personal relationship versus just another employee, but
9 either way.

10 **Q.** One of your fellow agents at DEA?

11 **A.** Yes, investigators, that's correct.

12 **Q.** Fellow investigators. This says Wright's supervisor,
13 Michael Mapes, told distributors at the DEA's Pharmaceutical
14 Industry Conference on September 11th, 2007 that the DEA's
15 new interpretation of the suspicious order regulation was
16 that the distributors should suspend shipments if they
17 routinely report suspicious orders with no reason to -- with
18 reason to believe they are destined for the illicit market.
19 Mapes informed Wright of that policy interpretation as well.
20 Do you see that?

21 **A.** I do.

22 **Q.** Did you take any issue with that testimony when you
23 were there?

24 **A.** I didn't at that time. I don't agree with it now.

25 **Q.** Well, do you have any facts that let you say

1 2017; is that right?

2 **A.** Yes, I do, Your Honor.

3 **Q.** All right. Let's cull that decision up. That's
4 DEF-WV-3532.

5 MR. SCHMIDT: And, again, Your Honor because it's
6 a court decision, we're not moving it into evidence. We're
7 asking the Court to take notice of it.

8 THE WITNESS: Thank you.

9 MR. SCHMIDT: Thank you.

10 And I will put it up on the screen absent objection.

11 BY MR. SCHMIDT:

12 **Q.** Do you see that this is a copy of the Masters decision
13 we were just looking at from the D. C. Circuit decided June,
14 2017?

15 **A.** Yes, I do, Your Honor.

16 **Q.** And I would like to show you just one portion of that
17 decision.

18 Could we go to Page 14, please? And if we could cull
19 out the paragraph in the bottom right corner.

20 And I want to look at the sentence that begins as noted
21 above. Do you see that sentence, Mr. Rafalski? As noted
22 above, the shipping requirement mandates that pharmaceutical
23 companies exercise due diligence before shipping any
24 suspicious order. Do you see that?

25 **A.** I do.

1 Q. And that's the do not ship requirement we've been
2 talking about, correct?

3 A. That's -- that's correct.

4 Q. Let's read the next sentence now. DEA first
5 articulated that requirement in Southwood, and Masters
6 claims that the administrator expanded on it here. Did I
7 read that correctly without the legal citation?

8 A. You did.

9 Q. And this opinion that you rely on, and cite in your
10 report, and actually worked on while at the DEA says DEA
11 first articulated that do not ship requirement in Southwood.
12 Remind us again when the Southwood decision was.

13 A. 2007.

14 Q. Thank you, sir. One more question on this topic. This
15 is in evidence for notice P-33. This is the first of the
16 two letters from Mr. Rannazzisi that you cited on your list
17 of guidance materials. You're familiar with this document,
18 sir?

19 A. I am, Your Honor.

20 Q. This is one of the two letters you cited as one of your
21 guidance materials?

22 A. It is.

23 Q. Dated September 27th, 2006?

24 A. Yes, it is, Your Honor.

25 Q. And it is from Joseph Rannazzisi, correct?

1 **A.** That's correct.

2 **Q.** So, this pre-dates that Southwood decision we just
3 talked about that the Masters decision says was the first
4 articulation of the do not ship requirement, correct?

5 **A.** I'd agree with that statement, Your Honor.

6 **Q.** All right. Let's look at this letter predating that
7 first articulation of the do not ship requirement. Would
8 you go with me to the second page, please? If we look at
9 the second paragraph, Mr. Rannazzisi writes, DEA recognizes
10 that the overwhelming majority of registered distributors
11 act lawfully and take appropriate measures to prevent
12 diversion. Did I read that correctly?

13 **A.** You read it correctly.

14 **Q.** Here's my question, sir. At this time, when Mr.
15 Rannazzisi said that the overwhelming majority of registered
16 distributors act lawfully and take appropriate measures to
17 prevent diversion from before this time period, before 2006,
18 is there any distributor you can point me to that blocked
19 every order it reported to the DEA?

20 **A.** I'm not aware of that, Your Honor.

21 **Q.** Switching gears. There's not a specific record
22 retention requirement under law for federal diligence files,
23 correct?

24 **A.** It doesn't -- in the Federal Register, it doesn't
25 specifically speak to due diligence files.

1 Q. It doesn't say how long they need to be maintained,
2 correct?

3 A. No. I believe that's one of the areas of the
4 maintenance of effective control is to prevent diversion to
5 keep those records to document your decisions and your
6 actions, but it doesn't specifically say that, Your Honor,
7 anywhere in the federal regulations.

8 Q. There are specific recordkeeping requirements for some
9 types of documents, right?

10 A. Yes, there are. They are a part of what's used to
11 control and to guide the -- keep the closed system intact,
12 required records.

13 Q. Just not for diligence files, correct?

14 A. There is not -- doesn't speak to due diligence files.

15 MR. SCHMIDT: Okay. Let's -- I have one more
16 small topic I can start. I'm not done. I've got more to
17 ask, but I can do one more small topic, Your Honor, or I can
18 --

19 THE COURT: We've got seven minutes before your
20 sand runs out of the glass here.

21 MR. SCHMIDT: I think I can get it done in the
22 seven minutes. If not, I'll pick up tomorrow.

23 Could we put back up the demonstrative? And could we
24 go to Page 7?

25 BY MR. SCHMIDT:

1 Q. This says number of transactions into Huntington and
2 Cabell County, West Virginia. Do you see that?

3 A. I do, Your Honor.

4 Q. Lists that number of transactions in the Huntington and
5 Cabell County for AmerisourceBergen, Cardinal Health,
6 McKesson, correct?

7 A. That's what it -- that's what it says, Your Honor.

8 Q. And it purports to do that for different periods of
9 time for each one of those, correct?

10 A. Yes. That was based on the transaction data that was
11 provided.

12 Q. Do you understand you're missing large numbers of
13 transactions into Huntington and Cabell on this slide?

14 A. Yes, I do, and the slide probably more accurately
15 should have said retail pharmacies.

16 Q. Okay. You're missing the VA, correct?

17 A. I am.

18 Q. You're missing other hospitals, correct?

19 A. Yes, hospitals. Only -- only data that's on display
20 for you, Your Honor, as retail pharmacies as customers.

21 Q. You're missing specialty pharmacies, like compounding
22 pharmacies?

23 A. Yes.

24 Q. Okay. And why did you limit this in this way? Why did
25 you exclude those categories when you wanted to talk about